Vol. 21, No. 3 • WINTER 2023

A MAGAZINE OF THE ALPHA-1 FOUNDATION

ALPHA-1-TO-ONE

Practical advice, personal experiences and pertinent news for people touched by ALPHA-1

The New Alpha1.org

As we approach the end of this year, I am compelled to reflect on the remarkable journey we've shared. Our fall season has been marked by enriching interactions and gatherings with the Alpha-1 community worldwide, symbolizing the collective strength we draw from our united efforts.

Our support programs have expanded throughout this period, offering a lifeline to patients and their families. We've broadened our range of resources, offering a wide variety that includes educational materials, support groups, and invaluable access to experts adept at navigating the complexities of Alpha-1. Our physicians' collaborations and interactions within the Alpha-1 community further underscore our commitment to driving positive change.

Noteworthy events, such as our Education days in Denver, Boston, and Raleigh, brought Alphas from different corners of the nation together. These occasions facilitated learning from our experts and provided a platform for Alphas to connect, sharing their individual journeys. The yearly Escape to the Cape Bike Trek in Cape Cod stood as a powerful affirmation of our community's resilience, mutual empowerment, and shared inspiration. Your strength fuels my determination, and each mile I ride is a tribute to you. Your inspiration empowers me to push forward!

We have made significant strides in research, propelling us towards cutting-edge treatments and therapeutic interventions. Collaborative efforts have led to groundbreaking discoveries, bringing us closer to effective treatments and, ultimately, a cure for Alpha-1.

In November, the annual Awareness Month allowed us to reach an unprecedented audience, educating the public and healthcare professionals about early diagnosis and effective management. Simultaneously, our participation in the EU Parliament meeting in Brussels underscored our commitment to international dialogue and collaboration.

Advancements in plasma awareness, advocacy efforts, and the ongoing campaign to gain co-sponsors for H.R. 4438: The John W. Walsh Home Infusion Act have showcased the impact of our collective advocacy.

Looking ahead, we promise to meet you where you are, fostering community engagement across all sectors. The events map on page 26 outlines our plans for the next 18 months, encompassing outreach to patients, researchers, and families, shaping a dynamic community.

Your generous contributions play a pivotal role in bringing us closer to the goal of finding a cure for Alpha-1. Each dollar is a beacon of hope, reinforcing that patients and families are not alone in their journey. Please see our year-end appeal on page 15 to learn more about how your gift makes an impact. As the year concludes, on behalf of the entire Alpha-1 Foundation team, I extend warm wishes for a joyous holiday season and a healthy, prosperous new year.

Best regards,

Scott Santarella
President & CEO

ALPHA-1-TO-ONE

Practical advice, personal experiences and pertinent news for people touched by Alpha-1, their families and friends

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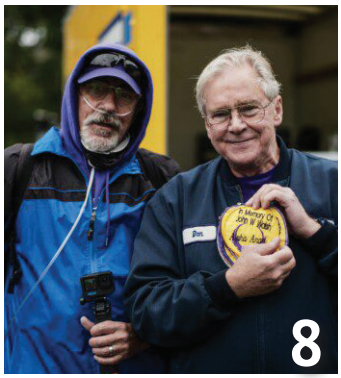
A MAGAZINE OF THE ALPHA-1 FOUNDATION

Inside ALPHA-1-TO-ONE



Features

STAY CONNECTED

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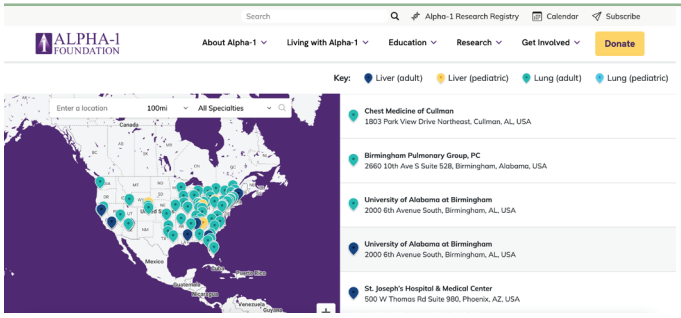
The New www.alpha1.org



In late August, the Alpha-1 Foundation announced the launch of the new and improved Alpha-1 Foundation website! The goal was to create a highly functional, information rich resource that offers a user-friendly experience for all visitors, from Alphas and their families to physicians and investigators. Redesigned with the Alpha-1 community in mind, the revamped alpha1.org features a simplified menu to help users navigate the site and easily find the resources they need.

The menu bar features five headings:

About Alpha-1: where you can find information and resources about the condition including What is Alpha-1?, Symptoms, Causes, Testing & Diagnosis, Lung and Liver Disease, Panniculitis, and Treatment.

Living with Alpha-1: where you can find resources for managing Alpha-1, find care through an Alpha-1 specialist, and get support through the Patient Information Line, the Peer Guide Program, Genetic Counseling, and Alpha-1 Support Groups.

Education: where you go to learn about Alpha-1 education events including Alpha-1 Education Days and the Alpha-1 National Conference, learning materials including a video library, resource library, and Alpha-1 Glossary of Terms, and Continuing Medical Education (CME) options available to help clinicians and healthcare providers learn about Alpha-1.

Research: where you can read about participating in research as a patient, grants available for Alpha-1 researchers, Research Initiatives, Research Resources available to investigators, and annual Scientific Meetings and Conferences.

Get Involved: Where you can discover ways to give to the Alpha-1 Foundation, fundraise for Alpha-1, advocate for yourself and the Alpha-1 community, and raise awareness of Alpha-1.

Some of the features included in the new and improved website include:

Video Library

An integrated and searchable video library where you can watch recent educational presentations from the Alpha-1 National Conference, Alpha-1 Education Days, and webinars. The new feature allows you to narrow your search for videos by event, topic and speaker.

Participate in Research

By participating in a clinical trial, you can help researchers discover and develop new treatments for Alpha-1. The Clinical Trials 101 page provides information regarding clinical trials happening in Alpha-1 and next steps for how you can get involved. The Alpha-1 Research Registry page shows the steps to join the Alpha-1 Research Registry and be part of the cure for Alpha-1.

Alpha-1 Specialists

Finding a doctor who specializes in Alpha-1 is an important part of managing your care. The upgraded map feature allows you to search for an Alpha-1 specialist in your area by zip code or city and categorizes specialists by adult liver, pediatric liver, adult lung, and pediatric lung.

Alpha-1 Support Groups

Alpha-1 Support Groups exist around the country to connect and assist Alphas and their caregivers in their local areas. The upgraded map feature allows you to search for an Alpha-1 Support Group near you by zip code or city.

25th Gordon L. Snider Critical Issues Workshop:
Z Variant Heterozygosity: Disease Risk and Treatment Implications

On October 27, 2023 the Alpha-1 Foundation held the 25th Gordon L. Snider Workshop titled **Z Variant Heterozygosity: Disease Risk and Treatment Implications** in Bethesda, Maryland. Co-chaired by Dr. Andrew Wilson, Dr. Craig Hersh and Dr. Jeffrey Teckman the workshop had a goal to understand the relative risk that MZ heterozygotes have for injury to either the liver or lung, and in what contexts, relative to those with no Z genes.

It is very common to have inherited one copy of the normal Alpha-1 gene (referred to as "M") along with an abnormal version of that gene (referred to as "Z", "S", or another variant) that contain the instructions for making alpha-1 antitrypsin, or AAT. Individuals with one normal and one abnormal copy of the AAT gene (referred to as "MZs") are also called "heterozygotes." AAT is normally produced in the liver and travels through the blood to protect the lungs and liver from inflammation. Historically, it has been assumed that heterozygotes, sometimes also termed "carriers", are symptom free or not predisposed to the clinical symptoms of Alpha-1. That is, having one normal allele was presumed to be protective. However, over time the Alpha-1 patient community has raised questions about the potential risk for lung and/or liver disease among individuals in this group. There is scientific basis for that concern as a growing body of evidence shows that some small fraction of MZs develop either lung or liver injury characteristic of Alpha-1. The challenges lie in identifying those who might be at higher risk among the large number of MZs who will never develop disease, determining whether treatments that are applied for ZZ Alpha-1 patients might be beneficial, and, if detected early, can measures be taken to prevent disease before it occurs?

The lack of sufficient evidence to clearly define risk for MZs has resulted in uncertainty for both patients and practitioners and variation in treatment approaches. This has not served the Alpha-1 community well. Because of the implications for the enormous number of individuals around the world who harbor a single Z gene, it is important to identify the relative risk of disease for this subpopulation and determine whether treatments being considered for ZZ individuals in upcoming clinical trials, if proven effective, might benefit MZs as well.

In 2017, the Alpha-1 Foundation and its partners convened a workshop to assess what was known about the MZ state and identify future lines of research into disease mechanisms and clinical features in MZ heterozygotes. That workshop concluded with the development of a series of research questions to pursue regarding the clinical implications of MZ status, and possible approaches for answering them. Over the past 6 years, more data have become available from studies around the world. The Foundation thought it was important to take another look at these issues and convened the workshop and included stakeholders from the research, pharmaceutical, and patient communities.

Scientific presentations highlighted that population-based and family studies of MZs reveal that when exposed to an environmental injury such as cigarette smoking, a proportion of these individuals have relatively higher risk for lung disease than do individuals with no Z variant. A similar situation exists for risk of liver injury. Evidence collected from human cells involved in inflammation in the lung and liver, mouse models of Alpha-1, and tissue from the livers of Alpha-1 patients who received a transplant provide clues to the disease mechanisms associated with Z heterozygosity. Early-stage research is focused on whether treatment strategies for ZZ patients are appropriate and beneficial for MZ individuals. Participants discussed clinical trials design and infrastructure needs to identify and study the MZ population.

In sum, the workshop underlined the need to reject the assumption that inheritance of a single Z gene does not increase disease risk among all MZs. Every day, more is being learned about the relative risks of lung and liver disease among this population but there is a lag in understanding viable treatment options because of an insufficient evidence base. Innovation is needed in study design, recruitment and enrollment strategies, and in facilitating the entire clinical trial process.

Winter Wellness: Your Questions Answered

Dr. Robert A. Sandhaus

Q: Can I get the influenza vaccine at the same time as the latest COVID vaccine? Or do I need to wait in between shots?

A: You can receive the latest COVID vaccine and the influenza vaccine at the same time. It is usually recommended you get one in each arm.

Q: Should an Alpha get the shingles vaccine?

A: Shingles is a terrible disease in terms of how painful it is, the scarring it can cause, and, when the an eye is involved, the possibility of blindness. Alphas should follow the same recommendations as the general public and consider getting the shingles vaccine when they qualify. The current recommendation is to receive the series of two vaccinations is if you are 50 years old or older.

Q: As an Alpha am I at higher risk for pneumonia? Should I get the pneumonia shot? And if so, do I need to space it out between the seasonal influenza and COVID vaccines?

A: The medical team recommends that all Alphas with lung or liver disease get the pneumonia vaccines. The timing recommendations are somewhat confusing depending on which pneumonia vaccine you might have already received and whether you have lung disease or not. The reason for recommending an Alpha receive the pneumonia vaccine series is that pneumonia (a bacterial or viral infection of the lung tissues) can lead to worsening emphysema if not prevented or rapidly treated.

Q: If I contract COVID this season, should I contact my doctor for a prescription?

A: COVID antiviral medications, like Paxlovid, are still highly effective at reducing the severity and duration of a COVID infection and there is growing evidence that such medications can also help prevent long COVID symptoms. It is a good idea to let you doctor know you've contracted COVID as soon as possible after a positive test, since the earlier you start one of these medications, the better they work.

Q: What is the best way to stay healthy all winter as an Alpha?

A: The best way to stay healthy is to use your 'Alpha Smarts' – know your body, follow reasonable safety precautions, and be aware of your surroundings. If you have lung or liver disease, wear a mask if you are in an indoor crowd of friends and/or relatives. Encourage invitees to stay home if they are not feeling well. And above all, stay away from cigarette smoke!

Join the Alpha-1 Research Registry

ALPHA-1 FOUNDATION
Research Registry

We are recruiting for Alpha-1 related studies and need your participation!

We encourage you and your family members to join the Alpha-1 Research Registry to help advance Alpha-1 research, diagnosis, and treatment.

Anyone diagnosed with Alpha-1 can join the Registry in three steps:

1. Complete a Registration Form
2. Review and Sign the Informed Consent
3. Complete the Questionnaire

To enroll or for more information:

alpha1.org/join-the-alpha-1-research-registry

The Alpha-1 Foundation Clinical Trials Education Program

Are you interested in better understanding how a study drug comes to fruition? From our Clinical Trials Education Program, you can learn more about different phases and types of clinical trials, how inclusion/exclusion criteria can affect participation in a study, what is informed consent and why it is important, and the next steps to get involved!

Visit our website for more information:

www.alpha1.org/clinical-trials-101

ALPHA-1 FOUNDATION

2023 Escape to the Cape

The Alpha-1 Foundation was proud to partner with the American Lung Association (ALA) for the 27th year of Escape the Cape in Massachusetts. Over 150 Alphas, friends and family came from all over the United States and joined together for two days to raise awareness and funds for Alpha-1. Riders participated in the in-person event on Cape Cod and during the month-long Riding for a Reason virtual riding campaign throughout September to raise over $136,000. Riders created teams and generated excitement on their online platforms to engage family and friends in raising dollars towards a cure.

Teams rode under the Team Alpha-1 umbrella including AlphaDogs (Captain: Jon Hagstrom), Keeping the Faith (Captain: Fred Walsh), Team Miami Office (Captain: Gordon Cadwgan), Team NY Alphas (Captain: Mike Allen), Team Alphas (Captain: Kari Black) Wheels on Fire (Captain: Deb Labud), Team Wheezy Riders (Captains: Siobhan Lestina and Dan Grimm), Team Helping Hands (Captains: Sherie Smith and Toya De Leon) Team Thomas Jr. who rode in Tampa, FL over the weekend (Captain: Jessica Brown) and Team Beam (Captain: Jordana Mora).

Other teams that were part of the pack: Boston University CREM Lab (Captain: Dr. Andrew Wilson), Columbia Alpha Team with a Dream (Captain: Dr. Jeanine D'Armiento), CSL Behring (Captain: Alex Hansel), Grifols (Captain: Garry Bouton) and Takeda (Captain: Sara Rosenberg).

The event kicked off on Friday, September 22nd where volunteers and riders joined together to organize registration packets, the Alpha Angels patches and coordinate the logistics for the weekend. Special shout out to our newest volunteers Rebecca Ivie Lebryk and Karin and Michael Pittsley who helped set up for our team's registration. The Alpha Angels patches are worn by the riders each year to memorialize Alphas in the community. The yellow and purple patches adorned the jerseys and helped remember why these events continue year after year.

> "For patients with Alpha-1, the importance of community and socialization is ever apparent when we participate together in live, in-person events like, Escape to the Cape and Riding for a Reason. Gathering as a community, supporting one another, welcoming new faces while embracing and reconnecting with old friends and families is inspirational and rewarding. I am so proud to be part of the Alpha-1 community and playing a role in leading Alphas and our stakeholders raising awareness and funds to find a cure," said Scott Santarella, President and CEO of the Alpha-1 Foundation.

An exciting new addition to this year's event was the use of GoPro cameras donated by Ruth and Gordon Cadwgan. Team captains were given the cameras to capture each leg of the trek. It was a fun way to showcase the event and recruit future riders.

Team Alpha-1 managed Rest Stop #3 with signage for social media posts and the infamous "Fluffer Nutter Sandwich". Kathi and Dan Coffin teamed up with their niece Rachel Sprunger and the Masterson Family to lead the Alpha-1 community at the rest stop. Bundled up and dressed in all purple, Team Alpha-1 took home the "Most Spirited Award" at the event. Thank you to all the incredible volunteers that braved the inclement weather brought in by Tropical Storm Ophelia that followed the event up the coast all weekend. A special thank you to Dan Coffin and Tom Binnall for being the official Alpha-1 truck drivers throughout the weekend. The Alpha-1 "Sweep", Kevin Slusser, ensured that all riders on Team Alpha-1 were safe throughout each leg of the route. We are extremely grateful for our longstanding New England trek members, Fred Walsh and Shirley Dennis for their tireless commitment decade after decade for this outstanding fundraising and volunteer campaign.

Leadership from across the Alpha-1 Foundation joined on the Cape for this annual event including Scott Santarella, President and CEO, Jon Hagstrom, Board of Directors Chair, Fred Walsh, Vice Board Chair, Dr. Robert A. Sandhaus, Clinical Director, Mark Delvaux, CFO, Gordon Cadwgan, Past Chair of the Board of Directors and Dr. Jeanine D'Armiento, Past Chair of the Board of Directors.

After 100 miles, the 80 riders crossed the finish line and earned Team Alpha-1 the ALA Silver Spoke Award for the largest team again this year. Each rider proudly received their medals at the closing ceremony for the event. Thank you to our newest volunteers, and those returning, we could not have done it without you.

Thank you to our top fundraising teams from Escape the Cape and Riding for a Reason, Team Grifols, Team BU/BMC, Alpha Dogs, Keeping the Faith, Beam Team, Thomas Jr., A1F Miami Office, Team Alpha, Wheezy Riders, NY Alphas, Team Biking for Beckett and Team Amanda Howard. A special thank you to our top fundraisers, Jon Hagstrom, Harry Long, Gary Bouton, Tom Dombrowski, Dr. Andrew Wilson, Kailey Walsh, Kevin Slusser, Scott Santarella, Ryan Schmidt, Chase Scott and Joe Reidy.

We look forward to next year at Escape to the Cape from September 27th to September 29th, 2024. Thank you to our Building Friends for a Cure sponsors, AlphaNet, CSL Behring, Grifols and Takeda.

Heather Allen:
From Alpha-1 Diagnosis to Coastal AlphaNet Coordinator

Heather Allen

In the scenic coastal town of Pismo Beach, California, Heather Allen, a patient with Alpha-1 Antitrypsin Deficiency (Alpha-1), has not only embraced her diagnosis but also transformed it into a journey of determination and service. Heather's story unfolds from the heights of Lake Tahoe to the sea level of Southern California, illustrating the profound impact of community support and the commitment to lead a healthy life.

Heather's journey with Alpha-1 began with a childhood marked by athleticism. However, as she recalls, the inability to run long distances and the unique pain in her lungs went ignored. It wasn't until her twenties, while enjoying outdoor activities in Lake Tahoe that her friends noticed her unusual breathing patterns at high altitudes. At 40, a 23andMe test and follow up testing revealed her ZZ genotype, confirming her Alpha-1 diagnosis after eight years of undiagnosed illness. Living at 7,000 feet above sea level in Lake Tahoe, Heather faced the challenge of managing her health with augmentation therapy and supplemental oxygen while at the same time raising her energetic 8-year-old daughter. Heather's family history further unveiled a pattern of lung and liver conditions, shedding light on the genetic aspect of her condition. The revelation about her family's medical history prompted her to become a support group co-leader in the Reno area, delving into the complexities of Alpha-1 to better understand the condition and educate others. Heather's commitment to the Alpha-1 community deepened after her diagnosis.

In 2018, Heather realized her health would require her to step back from her passion for teaching children. As Heather transitioned from being an educator, AlphaNet recognized her potential and offered her a position as a coordinator. Realizing the health advantages of living at sea level, she relocated to Pismo Beach after six months in her new role. Heather's goals as an AlphaNet Coordinator (ANC) revolve around providing comfort and reassurance to fellow Alphas. She emphasizes that living with Alpha-1 is not a death sentence but an ongoing commitment to making healthy choices. Her mission is to support each Alpha to the best of her ability.

For Heather, the most satisfying aspect of being an ANC is the knowledge that she is positively impacting the world. Drawing from her own terrifying diagnosis, she finds purpose in guiding others through the initial challenges of Alpha-1. Heather fondly remembers her first coordinator, Buzz, who inspired her to become more involved and provided guidance on maintaining a healthy lifestyle. Buzz's reassurance instilled in Heather the belief that a long and fulfilling life was possible with effort, even in the face of severe illness.

Heather reflects on the monumental decision to leave her support system and move to the beach with her daughter, all while dependent on 3-4 liters of oxygen. Working with AlphaNet and experiencing the effects of sea-level living firsthand, she took control of her health. The move proved transformative, healing her body and providing a renewed perspective on life.

Heather Allen's story is one of determination, community, and transformation. From the challenges of an Alpha-1 diagnosis to her role as an AlphaNet Coordinator, Heather exemplifies the strength of turning adversity into an opportunity for service. In Pismo Beach, she continues to inspire and support fellow Alphas, proving that life after an Alpha-1 diagnosis can be not just endured but embraced.

READY-TO-INFUSE

PROLASTIN® C LIQUID

alpha$_1$-proteinase inhibitor (human)

The #1 prescribed alpha-1 therapy for more than 25 years[1]

- **15-minute** infusion time
- **Proven** to effectively raise the alpha$_1$ antitrypsin protein levels in patients with severe alpha$_1$-antitrypsin deficiency, also known as alpha-1
- The **PROLASTIN DIRECT®** program gives you the confidence that ongoing personalized support is there for you when needed

Reference: 1. Data on file, Executive Summary, Grifols.

Steve M. and his wife, Ellen.
Steve has been on therapy since 2007.

Visit our website, **www.prolastin.com/LIQUID,** for more information and patient-friendly resources.

Important Safety Information

PROLASTIN®-C LIQUID is an alpha$_1$-proteinase inhibitor (human) (alpha$_1$-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha$_1$-PI (alpha$_1$-antitrypsin deficiency).

Limitations of Use

- The effect of augmentation therapy with any alpha$_1$-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in alpha$_1$-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials
- Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with PROLASTIN-C LIQUID are not available
- PROLASTIN-C LIQUID is not indicated as therapy for lung disease in patients in whom severe alpha$_1$-PI deficiency has not been established

PROLASTIN-C LIQUID is contraindicated in immunoglobulin A (IgA)-deficient patients with antibodies against IgA or patients with a history of anaphylaxis or other severe systemic reaction to alpha$_1$-PI products.

Hypersensitivity reactions, including anaphylaxis, may occur. Monitor vital signs and observe the patient carefully throughout the infusion. If hypersensitivity symptoms occur, promptly stop PROLASTIN-C LIQUID infusion and begin appropriate therapy.

Because PROLASTIN-C LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. This also applies to unknown or emerging viruses and other pathogens.

The most common adverse reactions during PROLASTIN-C LIQUID clinical trials in >5% of subjects were diarrhea and fatigue, each of which occurred in 2 subjects (6%).

Please see brief summary of the full Prescribing Information for PROLASTIN-C LIQUID on adjacent page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

GRIFOLS

February 2023 US-PRL-2300019

PROLASTIN®-C LIQUID

Alpha$_1$-Proteinase Inhibitor (Human)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROLASTIN-C LIQUID safely and effectively. See full prescribing information for PROLASTIN-C LIQUID.

PROLASTIN-C LIQUID
(Alpha$_1$-Proteinase Inhibitor [Human])
Solution for Intravenous Injection

Initial U.S. Approval: 1987

----------INDICATIONS AND USAGE----------

PROLASTIN®-C LIQUID is an Alpha$_1$-Proteinase Inhibitor (Human) (Alpha$_1$-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha$_1$-PI (alpha$_1$-antitrypsin deficiency).

Limitations of Use:

- The effect of augmentation therapy with any Alpha$_1$-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in Alpha$_1$-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials.
- Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with PROLASTIN-C LIQUID are not available.
- PROLASTIN-C LIQUID is not indicated as therapy for lung disease in patients in whom severe Alpha$_1$-PI deficiency has not been established.

----------DOSAGE AND ADMINISTRATION----------

For intravenous use only.

- Dose: 60 mg/kg body weight intravenously once per week.
- Dose ranging studies using efficacy endpoints have not been performed with any Alpha$_1$-PI product, including PROLASTIN-C LIQUID.
- Administration: 0.08 mL/kg/min as determined by patient response and comfort.

----------DOSAGE FORMS AND STRENGTHS----------

For injection: approximately 500 mg (10 mL), 1,000 mg (20 mL) and 4,000 mg (80 mL) of a solution for injection in single-dose vials.

----------CONTRAINDICATIONS----------

- Immunoglobulin A (IgA) deficient patients with antibodies against IgA.
- History of anaphylaxis or other severe systemic reaction to Alpha$_1$-PI.

----------WARNINGS AND PRECAUTIONS----------

- Severe hypersensitivity and anaphylactic reactions may occur in IgA deficient patients with antibodies against IgA. Discontinue administration of the product and initiate appropriate emergency treatment if hypersensitivity reactions occur.
- Because PROLASTIN-C LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

----------ADVERSE REACTIONS----------

The most common adverse reactions during PROLASTIN-C LIQUID clinical trials in > 5% of subjects were diarrhea and fatigue, each of which occurred in 2 subjects (6%).

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Dan Coffin helping to increase Plasma Donations and Awareness

Alpha Dan Coffin shared his story with the Plasma Protein Therapeutics Association (PPTA) to increase awareness of plasma donations and thank the donors for their commitment to saving lives each and every day. This campaign reached across the nation to also increase awareness of Alpha-1 Antitrypsin Deficiency. The press release reached a potential of 152 million people and had over 200 placements in the top metro markets across the U.S. and more than 600 were showcased on the front page.

Dan Coffin

Millions of people around the world rely on plasma to treat a range of conditions, including rare inherited diseases, severe burns and trauma, liver disorders, and for cancer-supportive care.
"Plasma-derived medicines are often the only therapies available for patients with many rare, chronic and potentially debilitating and life-threatening diseases," says Anita Brikman, President and Chief Executive Officer of the PPTA. "In short, donating plasma helps save lives."

To encourage individuals to learn more and to donate plasma, if they are eligible, the Plasma Protein Therapeutics Association is sharing patient insights, along with answers to some frequently asked questions about the uses of plasma in healthcare and why we need more of it:

Q: What is plasma and why is it so useful in treating such a broad range of health conditions?

A: Plasma is the single largest component of human blood, making up about 55% of blood volume. Plasma proteins help the body fight infection, clot blood and regulate blood pressure. Patients with certain genetic disorders are unable to make some of those critical proteins and antibodies, but they can be isolated from donated plasma and help compensate for that shortfall. Plasma-derived medicines can also be beneficial for individuals with a compromised immune system due to treatment for cancer or an organ transplant.

Q: Who benefits from plasma donations?

A: Medicines made from donated plasma help those with certain neurological, lung, bleeding and immune system disorders lead healthy, productive lives. Some of these rare conditions can be life-threatening without the right treatment. After noticing that it was hard to breathe during tasks such as shoveling snow and mowing the lawn, military veteran Dan Coffin was tested for and diagnosed with Alpha-1 Antitrypsin Deficiency, an incurable, inherited condition that may cause lung disease and liver disease.

"I went from being extremely physically fit to having trouble with simple tasks in the yard. The plasma protein therapy infusions I receive, thanks to the generosity of donors, make it possible for me to live an active and healthy life again," says Coffin.

Many others also benefit from plasma-derived therapies, such as trauma patients, organ transplant recipients, children with HIV, and anyone who has ever received a rabies or tetanus shot. Both treatments, which are often delivered after incidents such as being bitten by a wild animal or stepping on a rusty nail, are made from plasma that contains antibodies to those pathogens.

Additionally, for some mothers and babies, an incompatibility in blood type can result in severe anemia and jaundice in newborns unless the mother receives Rho(D) immune globulin made from plasma.

Q: Why are plasma-derived medicines unique?

A: Plasma-derived medicines are not like other pharmaceuticals. Plasma can't be made in a lab and it is not an infinite resource. It often takes hundreds of individual donations to collect enough plasma to create the medicine needed for a single patient each year. That's why patients who rely on these therapies are so dependent on donors.

Q: How can people donate plasma?

A: To learn more about donor eligibility and the donation process, and to find a local licensed and certified plasma donation center, visit donatingplasma.org.

"So many people know about donating blood, but they don't know about the need for donated plasma," says Brikman. "Plasma donations are vital in helping patients who rely on plasma-derived medicines to improve or save their lives. Donate plasma today and give someone the chance to live a happier and healthier life."

Giving Back
To Move Us Forward
ALPHA-1 FOUNDATION

MEET BECKETT,

In June of last year, Beckett was in the hospital receiving a life-saving liver transplant due to Alpha-1.

When his parents learned of his Alpha-1 diagnosis, they were overwhelmed and scared and needed help understanding what this meant for their young son. They quickly found the Alpha-1 Foundation and were connected to resources and experts to help them on their journey. The Foundation is there for them every step of the way.

Today, as you can see, Beckett is a growing, healthy boy! He and his family are raising funds for Alpha-1 research and programs. He knows that by giving back, he will help us move the mission forward.

When you support the Alpha-1 Foundation, you become integral to our life-changing work.

Your generosity matters more now than ever before. Please consider making a tax-deductible donation today. Your contribution, no matter the size, will make a meaningful impact. It will directly support crucial research initiatives, fuel education, and advocacy programs, and provide vital resources to those in need.

Your support is a beacon of hope for patients and families like Beckett's, reminding them they are not alone in their journey.

Will you join him in giving back to help us move forward? Visit: ***alpha1.org/donate***

2023 Alpha-1 Educational Scholarships

Each year the Alpha-1 Foundation awards Alpha-1 Educational Scholarships to Alphas and family members seeking to further their education. This year, ten scholarships were awarded to deserving individuals. Congratulations to these outstanding young adults.

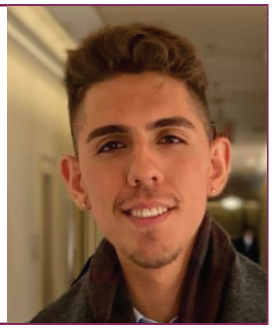
Aaron Layman and **Carlos Yanez Navarro** were awarded the **James (Jim) Quill Memorial Scholarships**. These scholarships honor the memory of Jim Quill. Jim served as an AlphaNet Coordinator, and then Manager of AlphaNet. Additionally, he served on the Alpha-1 Foundation's Board of Directors. He consistently solved problems for the entire Alpha-1 community. Not only was Jim the consummate mentor to all AlphaNet Coordinators and staff members, but he was always available to listen and offer counsel to any Alpha.

Aaron is a junior at the University of Toledo majoring in Mechanical Engineering and is from Ney, Ohio.

"My family was introduced to Alpha-1 ten years ago when my dad was diagnosed, and when we learned that my brother and I are carriers. We have continuously been learning about this condition and growing as a family in the face of challenges posed by Alpha-1. The ability to take a less than desirable obstacle and think about it in a good way makes Alpha-1 look like a battle that we are winning rather than something that we as a family are losing to."

"Living with the knowledge of Alpha-1's effects has made me well versed in the art of advocacy. Advocacy as a patient with doctors who do not know the condition well and as an advocate within my own family, where knowledge on genetics and their outcomes has been less than proficient. It has made me unafraid to advocate for my health, for my parents within the healthcare system, to get the care we need."

Carlos is a recent graduate from the University of Washington who majored in International Studies and is from Seattle, Washington.



Luke Moser was awarded the **Robert (Bob) J. Haggerty Memorial Scholarship**. This scholarship honors the memory of Bob Haggerty, who was the face and voice of the Alpha-1 Association for almost a decade. He served as Treasurer for many years, as well as Master of Ceremonies of the Alpha-1 National Conference.

Luke is a freshman at Ithaca College majoring in Sports Management and is from Chazy, New York.

"These challenges have helped me understand it is important to work hard and not give up when things become difficult. Though I have been faced with challenges, they have taught me to be thankful for all I have and push me to keep moving."

Jenna Russom was awarded the **John W. Walsh III (Jack) Memorial Scholarship**. This scholarship honors the memory of Jack Walsh, affectionately known as "Coach". Having celebrated 94 birthdays, Coach was an icon in the Alpha-1 community. Father to John, Fred, Judy and Sue, he perpetuated the importance of education and family within the entire Alpha-1 community.

Jenna is a senior at the University of Florida majoring in Microbiology and is from Jacksonville, Florida.

"One year ago, my father started augmentation therapy. Five months ago, I was conducting research on the SERPINA1 gene for college genetics class. Three weeks ago, I was offered a Student Research Assistant position at the University of Florida College of Medicine Alpha-1 Antitrypsin Genetics Laboratory. Two days ago, I received life-changing news: my own Alpha status; it was not easy finding out I had two Z alleles. However, as the realization sunk in, I did not feel any less alive. I felt inspired to do everything I could to change the future for myself, my father, and all who have had to hear the same prognosis."

Molly Scott was awarded the **E. Lou Glenn Memorial Scholarship**. This scholarship honors the memory of Lou Glenn, a dedicated caregiver of her daughter who was diagnosed with Alpha-1. An icon in the Alpha-1 community, she served on various committees, always supported programs for Alphas, and represented the voice of caregivers.

"With a compassionate heart and an endless curiosity, I will continue studying the phenomena of our bodies further. I hope my studies propel me towards my goal of becoming a part of the team that can further help soldiers with Alpha-1. Although we are no longer able to run together, I continue to run for the moment I see my dad's smile at the finish line."

Molly is a junior at Syracuse University, double majoring in Nutrition Science and Biochemistry, and is from Syracuse, New York.

Chase Noel was awarded the **Terry L. Young Memorial Scholarship**. This scholarship honors the memory of Terry Young, co-founder of AlphaNet who also served as the very first AlphaNet Coordinator. An icon in the Alpha-1 Community, he perpetuated the AlphaNet slogan, "Alphas serving Alphas."

Chase is a senior at Utah State University majoring in Finance and is from Cottonwood Heights, Utah.

"I learned many things from Alpha-1. I learned to face my fears head on. I learned that there are a lot of people out there struggling with life threatening conditions. I learned to let people support me. I learned that it's ok to be scared. I learned not to let my setbacks define who I am. I learned how much love my parents have for me. And I learned I can handle anything life throws at me."

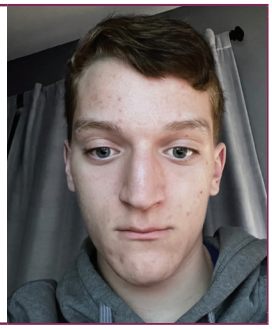
This year's Peter Smith Scholarships have been awarded to four deserving awardees, **Marisa Marvel, Evan Mescher, Austin Wagner** and **Audrey Woods**. Peter Smith wrote, edited and published Alpha-1 News from 1989 and 1992. Before his early death due to Alpha-1, he was spreading the word to over 1,200 households. His efforts encouraged, enlightened and inspired those with Alpha-1 to reach out to one another and to learn. The intent of the Peter Smith Scholarship is to continue this tradition by helping those with Alpha-1 and their families to learn and achieve.

Marisa is a freshman at Southern Virginia University majoring in Biochemistry, with a minor in Music, and is from Orem, Utah.

"I have wanted to go into the medical field my entire life, and my experiences have helped me decide that I might like to become a doctor and do research. If any of the work and research I plan to do could help people receive affordable and reliable treatments or cures to their ailments, I would feel so accomplished."

"Alpha-1 has had a profound impact on my life, teaching me valuable lessons about empathy, family, proactive healthcare, and resilience. While watching my mother struggle with this condition has been difficult, it has also helped me see the strength and beauty of the human spirit. I am grateful for my health and committed to supporting others who are dealing with chronic illnesses. By learning from my mother's experiences, I have become a better person and a more compassionate member of society."

Evan is a freshman at Purdue University majoring in Engineering and is from Cincinnati, Ohio.



Austin is a senior at Morehead State University majoring in Business Administration/ Accounting and is from Olive Hill, Kentucky.

"Living with Alpha-1 has also taught me the power of resilience and adaptability. This condition has presented me with numerous challenges, but instead of allowing it to hinder my life, I choose to view it as a motivator to stay on top of things and remain proactive about my health. This mindset has not only helped me manage my condition more effectively but has also translated into other aspects of my life, making me a stronger and more determined individual. For what I lack in Alpha-1-antitrypsin, I make up for in mental fortitude!"

"My experience as the daughter of an Alpha has inspired me to become an advocate for others. I have seen how important it is to speak up for those who are unable to do so for themselves and how much of a difference advocacy can make in people's lives. This experience has motivated me to pursue a career in law, where I hope to use my voice and skills to make a positive impact on the world. Witnessing my mother's struggles with a chronic and debilitating condition has shaped my perspective on life and has helped me become the person I am today."

Audrey is a senior at Amherst College majoring in Political Science and is from Longmeadow, **Massachusetts.**

The 2024 Alpha-1 Educational Scholarship Applications are opening soon!

Scholarships are available to Alphas and their immediate family members, and can be used for study at an approved institution for post-high school education and career change/returning adult students.

The application will be available in January and the deadline to submit a completed application with all attachments is **April 1, 2024**.

To learn more, visit **alpha1.org/alpha-1-educational-scholarships**

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alpha$_1$-proteinase inhibitor (Human)

Discover the ZEMAIRA difference...

CONVENIENCE of low-volume infusion in as little as 15 minutes*

PURITY achieved through rigorous and exacting manufacturing procedures†

EFFICACY proven in clinical trials to raise and maintain levels of the Alpha-1 protein

*Average infusion time is based on an infusion rate of 0.08 mL/kg/min for a 165lb patient. Individual experiences may vary.

†While all efforts are made to prevent transmission of infectious agents and viruses, the risk of transmission cannot be completely eliminated.

...and our commitment to Alphas.

Strengthened supply. Renewed confidence.
Announcing a reliable supply of ZEMAIRA thanks to the approval of an additional manufacturing site.

Talk to your doctor about ZEMAIRA and learn more at ZEMAIRA.com.

IMPORTANT SAFETY INFORMATION

ZEMAIRA®, Alpha$_1$-Proteinase Inhibitor (Human), is indicated to raise the plasma level of alpha$_1$-proteinase inhibitor (A_1-PI) in patients with A_1-PI deficiency and related emphysema. The effect of this raised level on the frequency of pulmonary exacerbations and the progression of emphysema have not been established in clinical trials.

Please see additional Important Safety Information and brief summary of prescribing information for ZEMAIRA on the following page.

ZEMAIRA is manufactured and distributed by CSL Behring LLC.
ZEMAIRA® is a registered trademark of CSL Behring LLC.

www.CSLBehring.com **www.ZEMAIRA.com** ZMR-0063-APR23

CSL Behring

IMPORTANT SAFETY INFORMATION (CONTINUED)

ZEMAIRA may not be suitable for everyone; for example, people with known hypersensitivity to components used to make ZEMAIRA, those with a history of anaphylaxis or severe systemic response to A_1-PI products, and those with certain IgA deficiencies. If you think any of these may apply to you, ask your doctor.

Early signs of hypersensitivity reactions to ZEMAIRA include hives, rash, tightness of the chest, unusual breathing difficulty, wheezing, and feeling faint. Immediately discontinue use and consult with physician if such symptoms occur.

In clinical studies, the following adverse reactions were reported in at least 5% of subjects receiving ZEMAIRA: headache, sinusitis, upper respiratory infection, bronchitis, fatigue, increased cough, fever, injection-site bleeding, nasal symptoms, sore throat, and swelled blood vessels.

Because ZEMAIRA is made from human blood, the risk of transmitting infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

Please see full prescribing information for ZEMAIRA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You can also report side effects to CSL Behring's Pharmacovigilance Department at 1-866-915-6958.

ZEMAIRA®, Alpha$_1$-Proteinase Inhibitor (Human)
lyophilized powder for reconstitution for intravenous use
Initial U.S. Approval: 2003

BRIEF SUMMARY OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ZEMAIRA safely and effectively. See full prescribing information for ZEMAIRA.

----------INDICATIONS AND USAGE----------

- ZEMAIRA is an alpha$_1$-proteinase inhibitor (A_1-PI) indicated for chronic augmentation and maintenance therapy in adults with A_1-PI deficiency and clinical evidence of emphysema (1).
- The effect of augmentation therapy with ZEMAIRA or any A_1-PI product on pulmonary exacerbations and on the progression of emphysema in A_1-PI deficiency has not been demonstrated in randomized, controlled clinical studies (1).
- ZEMAIRA is not indicated as therapy for lung disease patients in whom severe A_1-PI deficiency has not been established (1).

----------DOSAGE AND ADMINISTRATION----------

For intravenous use after reconstitution only (2).

- The recommended weekly dose of ZEMAIRA is 60 mg/kg body weight. Dose ranging studies using efficacy endpoints have not been performed with ZEMAIRA or any A_1-PI product (2).
- Administer through a suitable 5 micron infusion filter (not supplied) at room temperature within 3 hours after reconstitution (2.2).
- Do not mix with other medicinal products. Administer through a separate dedicated infusion line (2.2).
- Administer at a rate of approximately 0.08 mL/kg/min as determined by the response and comfort of the patient (2.2).
- Monitor closely the infusion rate and the patient's clinical state, including vital signs, throughout the infusion. Slow or stop the infusion if adverse reactions occur. If symptoms subside promptly, the infusion may be resumed at a lower rate that is comfortable for the patient (2.2).

----------DOSAGE FORMS AND STRENGTHS----------

ZEMAIRA is supplied in a single-dose vial containing approximately 1000 mg, 4000 mg, or 5000 mg of functionally active A_1-PI as a white to off-white lyophilized powder for reconstitution with 20 mL, 76 mL, or 95 mL of Sterile Water for Injection, USP. The amount of functional A_1-PI is printed on the vial label and carton (3).

----------CONTRAINDICATIONS ----------

- History of anaphylaxis or severe systemic reactions to ZEMAIRA or A_1-PI protein (4).
- Immunoglobulin A (IgA)-deficient patients with antibodies against IgA, due to the risk of severe hypersensitivity (4).

----------WARNINGS AND PRECAUTIONS----------

- Observe any signs of hypersensitivity such as tachycardia, hypotension, confusion, syncope, oxygen consumption decrease, and pharyngeal edema when administering ZEMAIRA to patients with known hypersensitivity to an A_1-PI product (5.1).
- Patients with selective or severe IgA deficiency can develop antibodies to IgA and, therefore, have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. If anaphylactic or severe anaphylactoid reactions occur, discontinue the infusion immediately (5.2).
- Because ZEMAIRA is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent (5.3).

----------ADVERSE REACTIONS----------

- Serious adverse reactions reported following administration of ZEMAIRA in pre-licensure clinical trials included one event each in separate subjects of bronchitis and dyspnea, and one event each in a single subject of chest pain, cerebral ischemia and convulsion.
- The most common adverse reactions occurring in at least 5% of subjects receiving ZEMAIRA in all pre-licensure clinical trials were headache, sinusitis, upper respiratory infection, bronchitis, asthenia, cough increased, fever, injection site hemorrhage, rhinitis, sore throat, and vasodilation (6).

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

Based on September 2022 revision

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You can also report side effects to CSL Behring's Pharmacovigilance Department at 1-866-915-6958.

Alpha-1 Pediatric Liver Roundtable

The Alpha-1 Foundation was proud to host a Pediatric Liver Roundtable Meeting on October 5, 2023 in San Diego, California during the NASPGHAN (North American Society for Pediatric Gastroenterology, Hepatology & Nutrition) conference. Pediatric Liver specialists were invited to join the Foundation for a robust discussion led by Scott Santarella, Dr. Jeffrey Teckman, Dr. Philip Rosenthal and Jon Hagstrom. The goal of the meeting was to bring together our new pediatric-liver Clinical Resource Center (CRC) members with existing members, introduce them to the Foundation and one another in-person and discuss how we can collectively continue to improve and advance the field on behalf of pediatric Alphas.

The meeting included a presentation on the current state of pediatric-liver care provided by Dr. Teckman, followed by a discussion on how to engage more pediatric-liver doctors to broaden access to care so parents of Alphas can find an expert within a reasonable traveling distance. The group also discussed ideas for bridging the gap between hepatologists and pulmonologists and improving communication and information sharing within CRCs to enhance patient care.

Ensuring Alphas get the best care possible is absolutely critical to maintaining health and wellbeing. The Clinical Resource Center program at the Alpha-1 Foundation connects Alphas with physician experts. Erin Carr, Alpha parent and Parents of Alpha-1 Kids Support Group leader is focused on expanding the CRC program to reach more Alphas closer to their homes. "Not all Alphas have the ability to travel hundreds of miles to get to a CRC but still deserve the best care possible. In 2023, the pediatric liver CRC program has expanded 2-fold and in 2024 I hope to provide the same for adult liver CRCs."

We are proud of the 83 CRC sites in the United States and Canada with 98 CRC physicians. These designated Clinical Resource Centers provide comprehensive care to Alphas, including specialized care for lung disease and liver disease. CRCs also play a critical role in helping the Foundation recruit patients for the Alpha-1 Research Registry. In addition, CRCs provide patients with resources and information needed to manage their Alpha-1. A comprehensive list of CRCs can be found at www.alpha1.org

"As the mom of a ZZ Alpha, I felt grateful that so many physicians are dedicating their lives to finding a cure for Alpha-1 and providing the best care possible for the littlest Alphas in the meantime. The atmosphere of the roundtable was open, and collaborative and I left feeling inspired and hopeful," said Erin Carr, Parent of Alpha-1 Kids (PAK) Support Group Leader.

We are excited to announce our newest Pediatric CRCs:

Cincinnati Children's Hospital Medical Center in Ohio
Akihiro Asia, MD, PhD
Kathleen Campbell, MD

Emory University School of Medicine,
Children's Healthcare of Atlanta in Georgia
Nitika Gupta, MD

Children's Hospital Los Angeles in California
Emily Gillet, MD
Rohit Kohli, MD, MS

UPMC Children's Hospital of Pittsburgh
in Pennsylvania
Simon Horslen, MD

Riley Children's Health, Indiana University
Healt in Indiana
Jean Molleston, MD

Glassia
[Alpha$_1$-Proteinase Inhibitor (Human)]

IT'S POSSIBLE TO

RAISE YOUR ALPHA-1 LEVELS

Prescribed by doctors for 10+ years, GLASSIA® has been proven to help increase Alpha-1 protein levels in the blood and lungs.*

*The effect of augmentation therapy on pulmonary exacerbations and on the progression of emphysema in Alpha-1 deficiency has not been conclusively demonstrated in randomized, controlled clinical trials.

Scan or visit **glassialiquid.com/getinfo** to learn more about GLASSIA and administration options.

"My pulmonologist recommended GLASSIA as the best option for me."

—**KATHY S.** Actual GLASSIA patient for ~2 years

After you and your physician choose a treatment path, OnePath® provides a range of personalized product support services throughout your GLASSIA treatment journey. For more information, visit **www.onepath.com.**

OnePath

What is GLASSIA?

GLASSIA is a medicine containing human Alpha$_1$-Proteinase Inhibitor (Alpha$_1$-PI) that is used to treat adults with lung disease (emphysema) because of severe Alpha$_1$-antitrypsin (Alpha$_1$) deficiency. GLASSIA is not meant to be used as a therapy for lung disease other than severe Alpha$_1$ deficiency. Effects of GLASSIA on worsening lung function and emphysema progression have not been proven in clinical trials. Long-term effects of Alpha$_1$ replacement and maintenance therapy have not been studied.

IMPORTANT SAFETY INFORMATION

What is the most important information I need to know about GLASSIA?

- GLASSIA can cause severe allergic reactions including hives, swelling in the mouth or throat, itching, tightness in the chest, trouble breathing, wheezing, faintness or low blood pressure
- If you will be taking GLASSIA outside a healthcare setting, ask your healthcare provider (HCP) about an epinephrine pen and/or other supportive care for certain severe allergic reactions.

Who should not use GLASSIA?

Do not use GLASSIA if you:

- Have immunoglobulin A (IgA) deficiency with antibodies to IgA
- Have a severe allergic reaction to human Alpha$_1$-PI products.

IMPORTANT SAFETY INFORMATION, CONTINUED

What are the possible or reasonably likely side effects of GLASSIA?

If any of the following problems occur contact your healthcare provider (HCP) or call emergency services right away:

- Worsening or flare-up of your chronic obstructive pulmonary disease (COPD)
- Hives, swelling in the mouth or throat, itching, chest tightness, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.

The most common side effects that may occur are headache and upper respiratory tract infections.

Other possible side effects of GLASSIA include:

- Cough
- Sinus infection
- Chest discomfort
- Dizziness
- Increased liver enzymes
- Shortness of breath
- Nausea
- Fatigue

These are not all the possible side effects. Tell your HCP about any side effect that bothers you or that does not go away. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Important Facts About GLASSIA on the next page.

Takeda

Glassia

[Alpha$_1$-Proteinase Inhibitor (Human)]

IMPORTANT FACTS ABOUT GLASSIA (glass-see-ă) [Alpha1-Proteinase Inhibitor (Human)]

Injection Solution – For Intravenous Administration

What is GLASSIA?

GLASSIA is a liquid medicine containing human Alpha1-Proteinase Inhibitor (Alpha1-PI) also known as alpha1-antitrypsin (AAT), which is purified from human blood. The main purpose of infusing GLASSIA is to increase the levels of the AAT protein in your blood and lungs. AAT protein protects the lung tissue by blocking certain enzyme-caused damage. Such damage can lead to severe lung disease, such as emphysema.

Limitations of Use:

- The effects of increasing the AAT protein levels with GLASSIA or any other Alpha1-PI product on worsening pulmonary function and progression of emphysema have not been proven in clinical trials.
- The long-term effects of AAT replacement and maintenance therapy with GLASSIA have not been studied.
- GLASSIA is not intended as a therapy in individuals with lung disease other than severe Alpha1-PI deficiency.

Who should not use GLASSIA?

Do not use GLASSIA if you:

- Have immunoglobulin A (IgA) deficiency with antibodies to IgA
- Have had a severe allergic reaction to human Alpha$_1$-PI products.

What is the most important information that I should know about GLASSIA?

Severe allergic reactions can occur with GLASSIA. Your doctor will inform you about signs of allergic reactions which include hives, swelling in the mouth or throat, itching, tightness in the chest, trouble breathing, wheezing, faintness, low blood pressure, or serious allergic reaction. If you have any of these reactions, discontinue use of the product and contact your physician and/or seek immediate emergency care, depending on the severity of the reaction.

If you or your caregiver will be administering GLASSIA outside a healthcare setting, ask your doctor about an epinephrine pen and/or other supportive care for certain severe allergic reactions. Ask your doctor to make sure you receive training on how and when to use any prescribed supportive care medicine and keep it close at hand when administering GLASSIA.

How should I take GLASSIA?

- GLASSIA is given directly into the bloodstream.
- You can get GLASSIA at your healthcare professional's office, clinic, hospital, or delivered directly to your home by a healthcare professional from a limited network of specialty pharmacy providers.
- Your healthcare professional will decide if self-infusion in your home is right for you. You should be trained on how to do infusions by your healthcare professional.

What should I tell my healthcare professional before I start using GLASSIA?

Before starting GLASSIA, tell your healthcare professional if you:

- Have IgA deficiency with antibodies to IgA.
- Have a history of severe allergic reactions to Alpha1-PI products.

What are the possible or reasonably likely side effects of GLASSIA?

- A possible side effect to GLASSIA is worsening or flare-up of your chronic obstructive pulmonary disease (COPD) in which your breathing gets worse than usual.
- Call your healthcare professional or go to your emergency department right away if you get: Hives, swelling in the mouth or throat, itching, chest tightness, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- The most common side effects are headache and upper respiratory tract infections. Other possible side effects of GLASSIA include: cough, sinus infection, chest discomfort, dizziness, increased liver enzymes, shortness of breath, nausea, and fatigue.

These are not all of the possible side effects for GLASSIA. You can ask your healthcare professional for information that is provided to healthcare professionals. Talk to your healthcare professional about any side effects that bother you or that don't go away.

How do I store GLASSIA?

Store GLASSIA refrigerated or at room temperature.

- You can store GLASSIA in the refrigerator (36°F to 46°F [2°C to 8°C]). Do not freeze.
- You can store GLASSIA at room temperature (up to 77°F [25°C]) for up to one month. You must use GLASSIA within one month once you remove it from the refrigerator. Do not re-refrigerate GLASSIA once the product has been stored at room temperature.
- Keep the GLASSIA vial in the box until you are ready to administer the product.

Check the expiration date on the carton and vial label. Do not use GLASSIA after the expiration date.

How do I get more information about GLASSIA?

The risk information provided here is not comprehensive. To learn more, talk about GLASSIA with your healthcare provider. The FDA-approved Full Prescribing Information including Information for Patients and Instructions for Use can be found at www.glassia.com or call 1-877-TAKEDA-7 (1-877-825-3327).

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Takeda

Cleveland Clinic

ALPHA-1 FOUNDATION

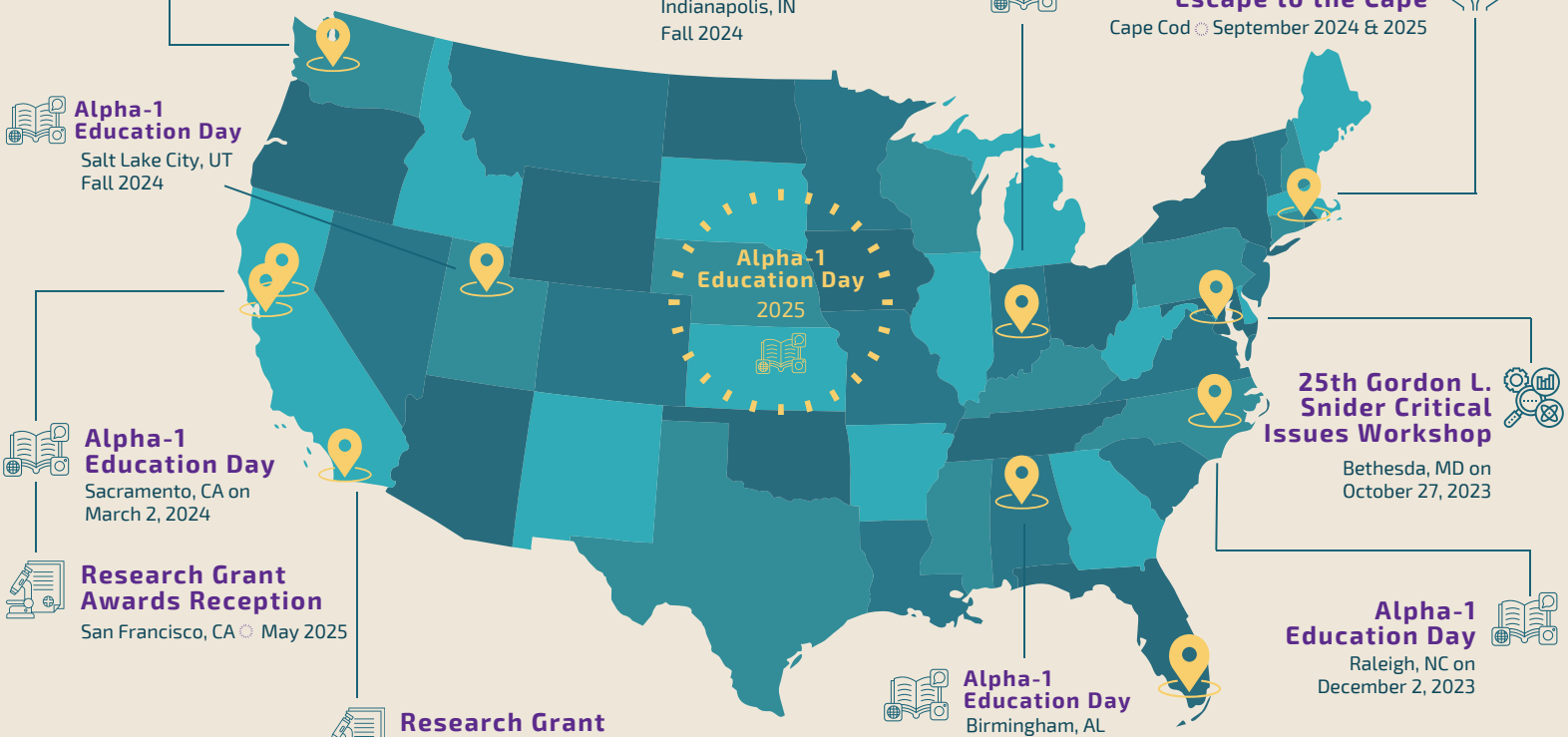
Alpha-1 Foundation Continuing Medical Education Series

The Alpha-1 Foundation is excited to announce that we are partnering with the Cleveland Clinic to create a new healthcare professional medical education series! Here are some highlights of the program. Take the course here: http://ccfcme.org/Alpha-1

- This educational series is designed to aid in the knowledge, diagnostic and treatment competence needs of healthcare providers to diagnose, treat, and provide better care for Alpha-1 patients.
- The professional education program targets various types of healthcare professionals, including, pulmonologists, hepatologists, pediatric lung, and liver physicians, liver and lung transplant physicians, nurse practitioners, physician assistants, genetics counselors, respiratory therapists, and internal medicine/general medicine physicians.
- Each video, as part of this series, includes a patient testimonial about their Alpha-1 experience.
- This online program has been approved for *AMA PRA Category 1 Credits™*
- The Foundation has partnered with Dr. Jamie Stoller and the Cleveland Clinic, which is accrediting the program, to develop this new healthcare professional, medical education program.

A big THANK YOU to patients, Dr. Stoller and his Cleveland Clinic team, members of the Foundation's Medical and Scientific Advisory Committee (MASAC), several board of directors of members, and Cleveland Clinic clinical staff who volunteered to record videos to help us create a robust Alpha-1 Foundation Continuing Medical Education Series.

Alpha-1 Foundation
2023-2025 Major Meetings & Events



Alpha-1 Education Day
Boston, MA on November 11, 2023

Celtic Connection
Boston, MA ◌ March 2024 & 2025

Riding for a Reason & Escape to the Cape
Cape Cod ◌ September 2024 & 2025

Alpha-1 Education Day
Seattle, WA on April 20, 2024

Alpha-1 Education Day
Indianapolis, IN
Fall 2024

Alpha-1 Education Day
Salt Lake City, UT
Fall 2024

Alpha-1 Education Day
2025

25th Gordon L. Snider Critical Issues Workshop
Bethesda, MD on October 27, 2023

Alpha-1 Education Day
Sacramento, CA on March 2, 2024

Research Grant Awards Reception
San Francisco, CA ◌ May 2025

Alpha-1 Education Day
Raleigh, NC on December 2, 2023

Research Grant Awards Reception
San Diego, CA on May 20, 2024

Alpha-1 Education Day
Birmingham, AL
Fall 2024

26th Gordon L. Snider Critical Issues Workshop
Miami, FL on March 22, 2024

Alpha-1 National Conference
Miami, FL ◌ June 21 to 23, 2024
Miami, FL ◌ June 2025

Investigators Meeting
Miami, FL ◌ October 2024

Clinical Resource Center (CRC) Forum
Miami, FL ◌ October 2024

Alpha-1 Leadership Meetings
Miami, FL ◌ October 2024

Alpha-1 Global

PORTUGAL

The Alpha-1 Global 6th Research Conference & 9th Patient Congress will take place April 2025 in Portugal.

LATIN AMERICA

2025 will feature a focus on Latin America, with resources toward engaging Alpha-1 patients and specialists.

ALPHA-1 FOUNDATION

To learn more about all Alpha-1 Foundation events in 2023, 2024 and 2025 including virtual events and initiatives, visit:
alpha1.org/calendar

Calendar of Events

www.alpha1.org | Alpha-1 Foundation | @alpha1foundation | @alphafriend | Alpha-1 Foundation

Are you receiving our emails?

Do you receive the monthly e-newsletter "Community Currents"? This is a good time to check to make sure that you are on our e-mail list. Update your contact information by visiting our new website www.alpha1.org

SUPPORT GROUP MEETINGS

Support groups are meeting both in-person and virtually on Zoom to provide everyone the support and education they need. To find your local Support Group and view the complete list of upcoming meetings, visit www.alpha1.org and the Events Calendar online.

To find your local Alpha-1 Support Group and view the complete list of upcoming meetings, visit the Events Calendar at www.alpha1.org

UPCOMING EDUCATION EVENTS

January 31, 2024	Alpha-1 Education Day	Virtual
March 2, 2024	Alpha-1 Education Day	Sacramento, CA
April 20, 2024	Alpha-1 Education Day	Seattle, WA
June 21-23, 2024	Alpha-1 National Conference	Miami, FL

For more information about the Alpha-1 Education Days, please visit www.alpha1.org

UPCOMING EVENTS

March 9, 2024	Celtic Connection	Boston, MA
September 27-29, 2024	Escape to the Cape	Cape Cod, MA

For more information about Building Friends for a Cure, please contact:
Angela McBride (877) 228-7321 ext. 233 or amcbride@alpha1.org

ALPHA-1 FOUNDATION
3300 Ponce de Leon Blvd. • Coral Gables, FL 33134

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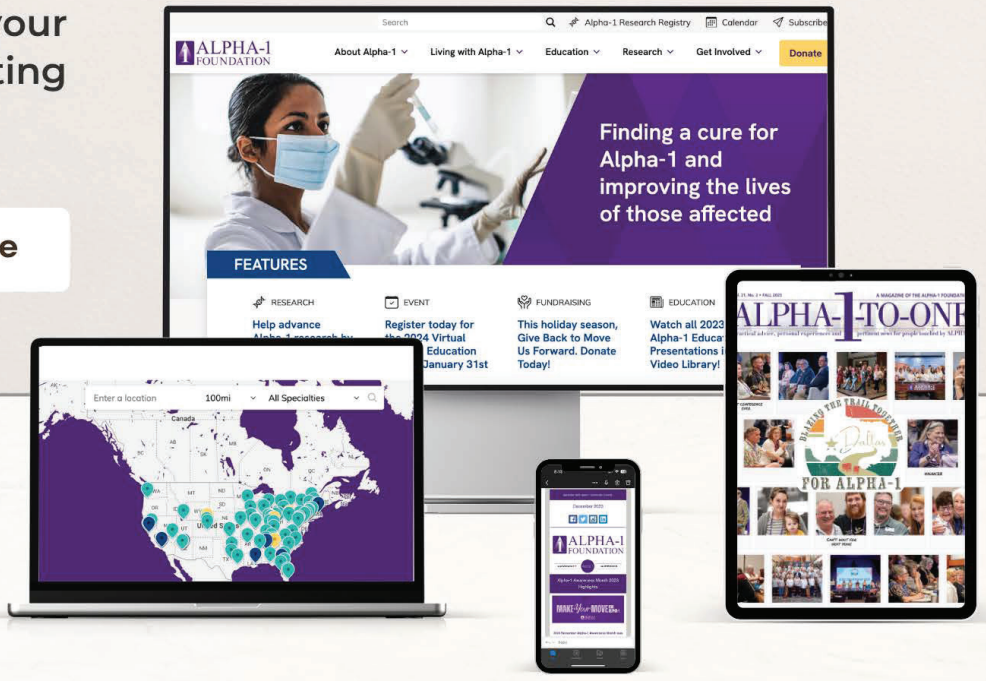

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