

# Acquired Thrombotic Thrombocytopenic Purpura (aTTP)

Acquired Thrombotic Thrombocytopenic Purpura (aTTP) is a life-threatening autoimmune blood clotting disorder with no previously existing pharmaceutical treatments. Pharm-Olam performed the pivotal trial for Ablynx which supported the marketing authorization for their Cablivi® product. ([see press release](#))

## Study Overview

Pharm-Olam completed a Phase III study of Cablivi™ (caplacizumab), a novel Nanobody® based drug for the treatment of aTTP.

## Therapeutic Area

Hematology

## Patient Population

145

## Sites & Locations

92 sites across 16 countries

## Services Provided

- Regulatory
- Clinical Monitoring
- Project Management
- Medical Writing
- Medical Monitoring

## Status

Study complete

## Recruitment & Site Selection

The initial recruitment target for this study was 92 patients, with a deadline of April 17. However, Pharm-Olam surpassed this goal and ultimately recruited 145 patients by the deadline.

## Recruitment Strategies

- Mapping patient landscape/coordinating local ER handoffs
- Providing site and patient flexibility
- Instructional aids for patient drug self administration
- Leaflet, poster and instruction guide for patients
- Monthly pre-screening logs
- Easing patient participation by utilizing home nursing aids
- Motivational visits
- Newsletter and WebEx

A complex patient consent process: aTTP onset is typically sudden and patients commonly are unconscious when they reach the emergency room. Pharm-Olam and the sponsor had to develop a repeatable and consistent process for sites to follow that would support the consenting and/or re-consenting of patients pending their situation (level of consciousness) and potential involvement of a legal guardian. The consenting process also had to account for country specific requirements, spanning 16 countries.



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Press Release](#)

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Country	Total Activated Sites	Total Patients Estimated	Enrolled Patients
Australia	6	8	3
Austria	1	3	4
Belgium	4	7	8
Canada	4	6	13
Czech Republic	4	2	4
France	9	14	12
Germany	9	6	—
Hungary	2	8	7
Israel	7	5	6
Italy	5	9	10
Netherlands	4	4	1
Spain	6	8	14
Switzerland	2	2	1
Turkey	6	8	9
United Kingdom	4	13	21
United States	19	29	32
<b>TOTALS</b>	<b>92</b>	<b>132</b>	<b>145</b>

## Keys To Success

- Careful site selection and mapping patient intake landscape (collaborating with ERs)
- Supportive/effective recruitment strategies and CRO staff availability (weekends)
- Follow-up with top recruiter sites and ensuring they were sharing their experience with the rest of the team
- Sharing successes at top sites so all sites can learn and contribute/enroll

*“Helping to bring a new treatment to patients is something we can be immensely proud of. We also want to congratulate Ablynx. This is not only the first therapeutic drug for the treatment of aTTP, it’s the first Nanobody® -based medicine on the market.”*

— DAVID GRANGE, PHARM-OLAM CEO

For more information about Pharm-Olam, please visit [www.pharm-olam.com](http://www.pharm-olam.com)

## About Pharm-Olam International

Pharm-Olam is Helping Create a Healthier World as a global, mid-sized CRO that offers flexible, innovative and highly personalized clinical solutions to pharmaceutical, biotechnology and life science companies. Our team is well-known for producing quality results with reduced risk, costs and timelines in challenging international trials. Offering full-service solutions and deep expertise in oncology, infectious diseases and vaccines, rare and orphan diseases.