

# The STATus Report

Seabreeze STAT Asthma (CBP-201-206) Update

Volume 2 – Issue 2

February 2026 Topics:

- ❖ Enrollment Updates
- ❖ Questions & Answers
- ❖ Study Updates and Reminders

## Monthly Message

February is a month dedicated to both Heart Health Awareness and the celebration of Valentine's Day. This focus on care and wellness serves as a meaningful reminder of the vital role research plays in improving the well-being of patients living with chronic conditions, including respiratory diseases like asthma.

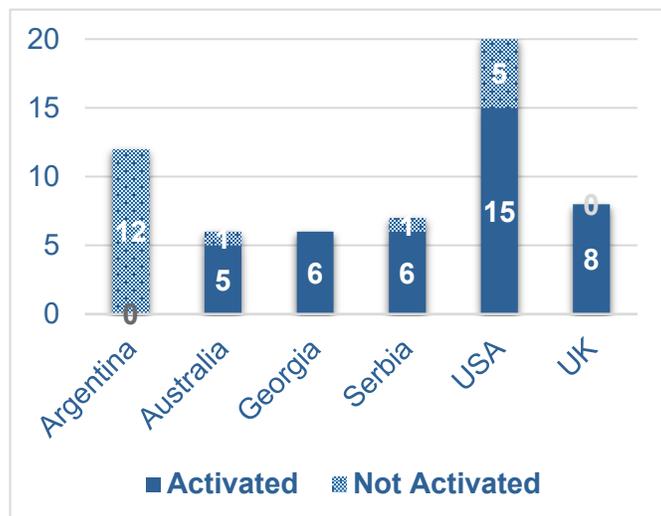
We have made significant strides in the Seabreeze STAT Asthma study by **AGAIN** doubling the number of randomized-participants! Thank you so much for your commitment and dedication to this study. Keep up the great work!

**Congratulations to Drs. Bosch and Djuric for randomizing their very first participant!**

We have made significant progress in activating sites across all regions. We look forward to activating our first sites in Argentina in the coming days.

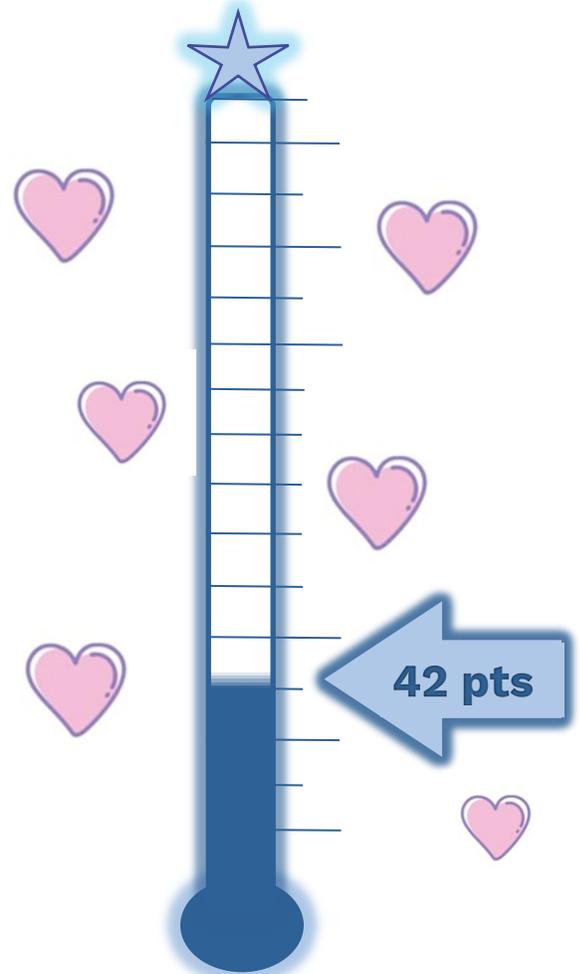
## Site Activations

(as of 13 February 2026)



## Enrollment Update

Goal = 160 Patients



### Top 3 Sites to Randomize

- ❖ Site 1402-Dr. Peikrishvili
- ❖ Site 1301-Dr. Čekerevac
- ❖ Site 1406-Dr. Shvelidze

# In Focus: Clinical Brief

## Question & Answers

**Q: Should asthma exacerbations be reported as adverse events?**

**A:** Acute asthma exacerbations are an efficacy endpoint in the study. All participants must have had at least a moderate asthma exacerbation (*i.e.*, requiring systemic steroids) to enter the trial. Section 11.3.1 of the protocol states the expected progression, signs, or symptoms of the disease or disorder being studied should not be recorded as an AE unless they become more severe or occur with a greater frequency than expected for the participant's condition. Therefore, all asthma exacerbations should not be listed as an adverse event.

A hospitalization or ED visit because of an asthma exacerbation, requiring systemic corticosteroids, would generally qualify as a Serious Adverse Event if more severe or occurs with a greater frequency than expected.

For those participants on OCS at the start of the trial, only a  $\geq 2$ -fold increase in dosage in response to symptoms will fulfill the definition of exacerbation.

**Q: For channel 1 (stable condition) participants, can visit 1a labs be used for the eosinophil count of  $\geq 250$  cells/ $\mu$ L inclusion criteria?**

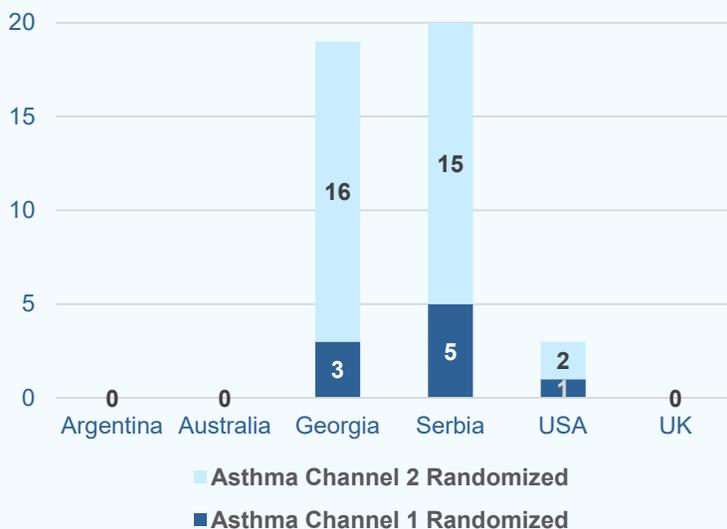
**A:** Yes, it is clarified in **protocol-version 4.0** that a peripheral blood eosinophil count of  $\geq 250$  cells/ $\mu$ L and/or a FeNO  $\geq 25$  ppb is required within 12 months prior to or at Screening Visit 1a.

**Q: Do patients need a physician to have diagnosed asthma  $\geq 12$  months ago to be eligible?**

**A:** The investigator should confirm and document the patient has asthma. If a patient reports having had asthma symptoms that have been treated for  $\geq 12$  months, a diagnosis documented in the medical records is not required to meet this inclusion criterion.

## Randomizations per Region (as of 13 February 2026)

Randomizations Per Region



## Reminders/Updates

- ❖ **Lab Kits:** Review your lab kit inventory and kit expiration, at minimum, monthly. Order at least **4 weeks** in advance.
- ❖ **Spirometry:** Order additional spirometry supplies at: [www.zephyrx.com/seabreeze](http://www.zephyrx.com/seabreeze).
- ❖ One row on the spirometry page should be completed for each protocol-required pre-BD and post-BD assessment.
- ❖ Apply visit ID labels in eCOA and in-clinic FeNO in the ZephyRx provider dashboard.
- ❖ **eCRF:** Asthma should not be listed on the Medical History form.
- ❖ **Data Cut:** The Connect team is preparing for a Data Monitoring Committee Meeting in March. Please complete data entry in EDC within 5 days of each participant visit.

## Seabreeze STAT Asthma Resources

Check out [seabreezestatasthma.com](http://seabreezestatasthma.com) for:

- ❖ Protocol/Amendments and Operational Manuals (Lab, Pharmacy, CCGs)
- ❖ Safety Reporting Forms and Study Team contact information



# Protocol Amendment 4.0

Protocol amendment version 4.0 was recently published by Connect Biopharma on 22 January 2026.

This protocol amendment reflects the valuable input received from sites to simplify enrollment and reduce operational friction. It also includes many clarifications based on questions received from study sites. All protocol amendments are driven by our commitment to supporting your success.



**RADEMNIKIBART**  
**PROTOCOL CBP-201-206**  
**A Phase 2, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Rademnikibart as an Add-on Treatment for Acute Exacerbation in Adult and Adolescent Participants with Asthma and Type 2 Inflammation**

**Seabreeze**  
STAT PROGRAM

Investigational Product:	Rademnikibart (CBP-201)
Protocol Number:	CBP-201-206
IND #:	154008
Development Phase:	2
Sponsor:	Connect Biopharma LLC (dba, Connect Biopharma) 1500 Coastal Meadows Road, Suite 200 San Diego, CA 92130 USA
Version and Date:	4.0, 22 January 2026

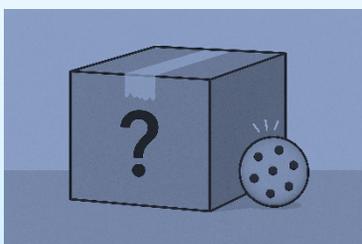
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CHANGE	RATIONALE
Added 1 day window for Visit 5	To assist with weekend scheduling
Reduced the number of required local laboratory tests at V1b	Minimized to essential tests only to assess participant eligibility for operational efficiency. See footnote “p” in the schedule of assessments.
Added flexibility in timing of prior exacerbation to “approximately” 12 months prior to screening	To capture historical exacerbations that occur very shortly before 12 months prior
For channel 1 participants (stable condition): added “approximately” to the screening period duration	To capture index exacerbations that occur very shortly after 26 weeks
Included multiple minor clarifications	To address frequently asked questions

## WE WANT TO HEAR FROM YOU!!

What would be helpful for your site to read about in future newsletters?  
 Please email us at [Clinical206@connectpharm.com](mailto:Clinical206@connectpharm.com).



### Mystery Package Alert

Many of you may have already received your package. We’ve cooked up a little thank you—a small dose of sweetness to celebrate a team that makes a big impact. A huge **THANK YOU** for your dedication to the Seabreeze STAT Program and for helping bring hope to patients. We appreciate you!