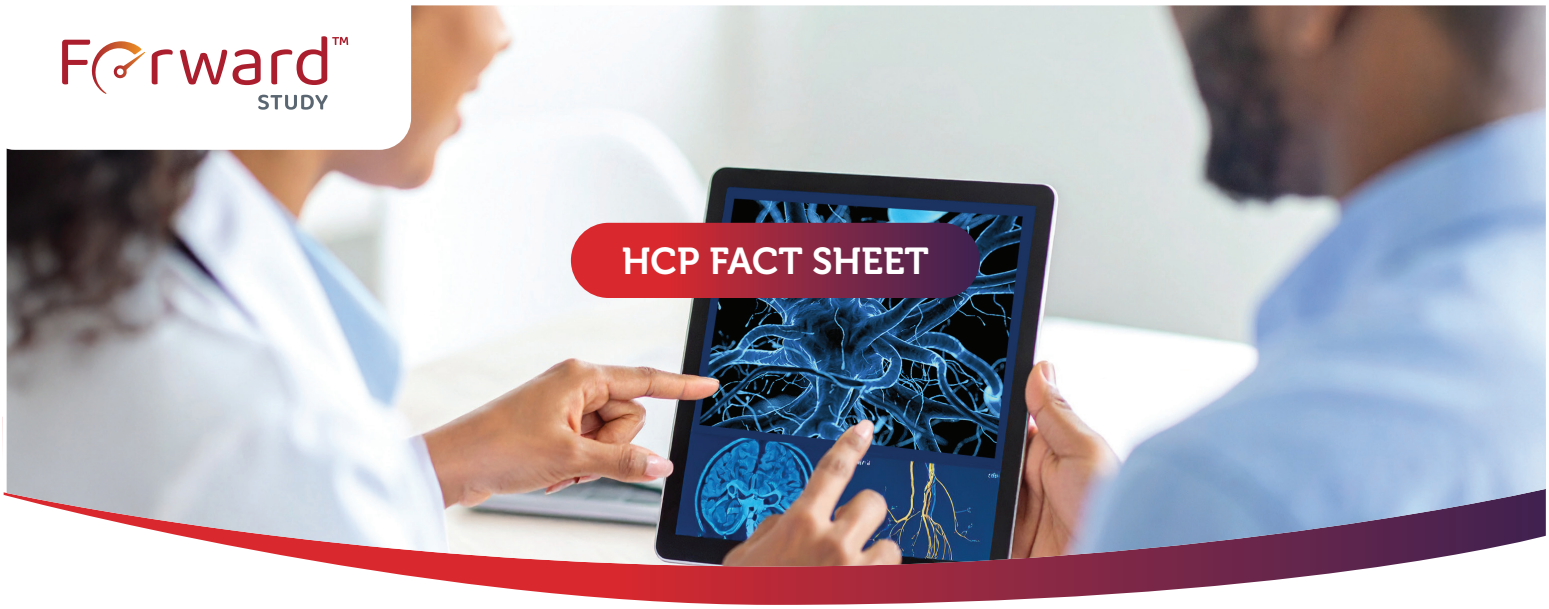
Forward™ STUDY



The FORWARD study

An open-label study to evaluate the pharmacokinetics, pharmacodynamics, efficacy, and safety of a single dose of tanruprubart (ANX005) in participants with Guillain-Barré Syndrome (GBS).

About GBS

- A rare, serious, and life-threatening medical emergency.
- Key clinical features:
  - Symmetrical, ascending weakness, often developing first in the legs
  - Sensory symptoms (prickling, tingling, numbness)
  - Autonomic dysfunction
- There is significant morbidity, long-term disability, and mortality associated with GBS despite off-label use of current standard of care therapies:
  - Intravenous immunoglobulin (IVIg) and plasma exchange (PE)

Tanruprubart: an investigational single-dose therapy

- Tanruprubart is a single-dose monoclonal antibody treatment that aims to reduce damage and inflammation by inhibiting C1q, the initiator of the classical complement pathway, and preventing its binding to peripheral nerves
- Tanruprubart is not currently approved by the FDA
- There are favorable results from previous studies with tanruprubart in other countries that warrant a bridging study in North America and Europe
  - There is a limited time window to stop the active disease process and achieve a therapeutic effect. Tanruprubart 30 mg/kg has been shown to inhibit the classical complement pathway on Day 1. It is thought to provide C1q engagement and ~1 week duration of inhibition

About the FORWARD study

- Target number of participants: 30
- Study duration per participant: 26 weeks
- Planned number of study centers: 26 in North America and Europe

Key inclusion criteria:

- ✓ Diagnosed with GBS according to NINDS diagnostic criteria
- ✓ 12 to 85 years of age
- ✓ **Onset of GBS-related weakness 10 days or less before Day 1 infusion**
- ✓ **GBS-Disability Score (GBS-DS) of 3, 4, or 5 at Screening and before Day 1 infusion**

Key exclusion criteria

- ✗ History of autoimmune disorder or a previous episode of GBS
- ✗ **Previous or planned treatment with either IVIg or PE within 90 days of Day 1**

The safety of tanruprubart is still being evaluated. It is a monoclonal antibody and may cause immune-related adverse effects. The investigator will review the potential benefits and risks with the patient.

Results of previous studies

Phase 3 study in GBS

Study design and population	Sample size	Topline results
• Randomized, double-blind, placebo-controlled • Age 16 to 85 years • Baseline GBS-DS score 3-5 • GBS diagnosed <10 days from onset of weakness • Electrophysiology showed approximately: – 20% acute inflammatory demyelinating polyneuropathy – 62% acute motor axonal neuropathy – 17% other	N=241	• Met primary endpoint: GBS-DS at week 8 • Compared with patients on placebo, treated patients: – were 2.4 times more likely to be in a better state of health measured using GBS-DS at week 8 (p=0.0058) – were walking 31 days earlier: treated = 56 days vs placebo = 87 days (p<0.0001) – spent 28 days less on ventilation: treated = 20 days vs placebo = 48 days (p=0.0356) • At week 1, tanruprubart demonstrated an 8.8-pt improvement in muscle strength (as measured by Medical Research Council sumscore) vs placebo (p<0.0001) • The most common adverse effects were infusion-related reactions. Typically, these involved rash. Some participants experienced tachycardia or hypotension which were easily treated.

Real-world evidence study comparing tanruprubart to IVIg or PE in matched patients from the International GBS Outcomes Study (IGOS) in GBS

Study design and matching	Sample size	Topline results
• Propensity-matched, external standard of care-treated cohort study • Real-world patients treated with IVIg and PE from the IGOS global patient registry matched based on key prespecified prognostic factors to Phase 3 study patients	N=79	• Compared with matched patients, patients treated with tanruprubart were: – approximately twice as likely to be in a better state of health, as measured by GBS-DS throughout the study, including at week 8 (p=0.0459) – less likely to require mechanical ventilation: treated n=15 vs matched n=32 of 79) (p=0.022)

Find out more

If you have any questions or require further information, please contact:

Contact person/Role/Phone Number:

You can also learn more by visiting theforwardstudy.com.