

If you see a potential study candidate, please contact the study staff immediately. Patients who have an acute ischemic stroke (AIS) with large hemispheric infarction (LHI) may qualify for this study. **Study drug treatment infusion should be initiated ASAP but no later than 10 hours after time of symptom onset (if known), or last known normal (if time to symptom onset is unknown), including wake-up stroke (refer to inclusion #8 in the protocol).**

## A PHASE 3 STUDY FOR SEVERE CEREBRAL EDEMA IN LARGE HEMISPHERIC INFARCTION (LHI)

Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Phase 3 Study to Evaluate the Efficacy and Safety of Intravenous BIIB093 (Glibenclamide) for Severe Cerebral Edema following Large Hemispheric Infarction (LHI)

### Main Inclusion Criteria\*:

- 18 to 85 years of age with a clinical diagnosis of acute ischemic stroke in the middle cerebral artery (MCA) territory  
**Note:** Older age cap has been reached, only subjects  $\leq 70$  years can be enrolled.
- Large hemispheric infarction (LHI) defined as lesion volume of 80 to 300 cm<sup>3</sup> on MRI (DWI) or CTP, or an ASPECTS score of 1 to 5 with involvement of at least 2 defined cortical regions
- Screening NIHSS  $\geq 10$
- Study drug treatment infusion within 10 hours after time of symptom onset (if known) or the time last known normal, including wake-up stroke (refer to inclusion #8 in the protocol)
- For subjects who receive thrombectomy, inclusion into the study must be based on post-thrombectomy MRI-DWI

### Main Exclusion Criteria\*:

- Likely to have supportive care withdrawn in the first day
- Commitment to decompressive craniectomy (DC) prior to enrollment
- Evidence of concurrent infarction in the contralateral hemisphere sufficiently serious so as to affect functional outcome

\*Please note that additional criteria may apply and the criteria listed above are not final and may be subject to change.

**For further information, please contact:**

BIIB093 is an investigational drug that is not approved by any health authority and its safety and effectiveness have not been established.



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