

Technology information form

Technology title
BNG-1 – Treatment for ischemia stroke
One sentence description of technology
A novel mixture of traditional Chinese medicines with anti-platelet aggregation and anti-thrombotic activity for both prevention and treatment of cerebral stroke.
Development status
Early stage ___ Preclinical ___ Phase I ___ Phase II ___ Phase III _X in Taiwan_ Phase IV ___ Preregistration ___ Registered ___
Full description (Less than 400 words)
<p>BNG-1, a drug candidate being derived from a novel mixture of traditional Chinese medicines, has shown the following preclinical pharmacologic activity:</p> <ol style="list-style-type: none">1. BNG-1 at 300 g/ml inhibited arachidonic acid-induced platelet aggregation in vitro.2. BNG-1 (1000 mg/kg x 8) prolonged 60.4% of bleeding time in mice in vivo.3. BNG-1 [(1 g/kg orally for 10 consecutive days beginning 7 days before and 3 days after middle cerebral artery occlusion (MCAO), (1 g/kg beginning 7 days after MCAO) exhibited 44% and 55.8% acute neuroprotection effect on rats with middle cerebral artery occlusion (MCAO), respectively.4. BNG-1 inhibited phosphodiesterase (PDE) isoforms with potency order of the following rank: PDE1> PDE3> PDE6> PDE2> PDE4>PDE5.5. Through an extensive safety pharmacology assessment of high doses of BNG-1, no threat to the normal vital functions of the cardiovascular, renal, respiratory or central nervous system in the animals was discovered. <p>Phase II clinical trials (under the regulations for new drugs from Taiwan's Department of Health (DOH), Bureau of Pharmaceutical Affairs), confirmed the safety and feasibility of BNG-1 consumed together with aspirin in patients with acute ischemic stroke, with no adverse effects in humans shown.</p> <p>In Taiwan DOH Phase III trials, a combination of BNG-1 and aspirin in treating acute ischemia stroke showed a more favorable response than aspirin alone at the end of</p>

week 12 of the study, according to the following criteria:

- a. Survival of the patient
- b. Modified Rankin Scale < 3 (determining ease of patient movement)
- c. Barthel Index \geq 60 (degree of ease in performing common daily activities)

Subjects were classified into two subgroups: older (age \geq 65 years old) and younger (age<65 years old). For the younger subgroup, patients who were administered a combination of BNG-1 and aspirin had a significantly more favorable response, according to the criteria above, than patients treated with aspirin alone (BNG-1 group: 53.6%, Aspirin group: 14.3%) (53.6% compared to 14.3% in ITT, p-value=0.0307, and 66.7% compared to 9.1% in PP, p-value=0.0280) (P<0.05%).

Additional clinical studies may be required for registration in other countries.

Patent status and no.

1. Taiwan: Patent No. I 275396
2. China: Patent No. ZL 01 1 36770.9
3. Singapore: Patent No. 111058
4. Malaysia: Patent No. MY-128772-A
5. Japan: Patent No. 3930365
6. Korea: Patent No. 0502947
7. U. Patent: No. US 6,936.282 B2
8. US: Patent No. US 6,872.409 B2
9. Australia: Patent No. 783302
10. Europe: Patent No. 1358887

Type of business relationship sought

All can be considered; licensing, co-development, etc.

Licensing contact

Karin Huang
General Manager
Braingenesi Biotechnology Co., Ltd.
1F, No. 83, Yu-Cheng St., Taipei, Taiwan

Tel: 886-2-2785-4780

Fax: 886-2-2785-4819

Email: info@braingenesis.com.tw

More information available on the web (company website)

<http://www.braingenesis.com.tw>