

## WH-1 Technology information form

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| Technology title  |
| WH-1: A botanical drug for the treatment of diabetic foot ulcers and the management of similar chronic wound healing conditions   |
| One sentence description of technology  |
| A botanical drug, WH-1, has been approved for US FDA Phase II clinical trials for the treatment of diabetic foot ulcers and also potentially indicated for similar chronic wound healing management conditions.   |
| Development status  |
| Early stage <input type="checkbox"/> Preclinical <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input checked="" type="checkbox"/> (US FDA and Taiwan DOH)<br>Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Preregistration <input type="checkbox"/> Registered <input type="checkbox"/>  |
| Full description  |
| <p><b>Diabetic drug enters 2nd-stage human testing</b></p> <p>A new Traditional Chinese Medicine (TCM) herbal medication for treating diabetic-induced chronic wounds, named WH-1, has been approved by the US FDA to enter second-stage human testing. WH-1 is composed of two Chinese herbs, including one that is relatively rare and growing in Taiwan. WH-1 has been assessed to be very competitive on the world market as a chronic wound-healing agent as it is cost effective to manufacture and has a superior stability profile.</p> <p>With diabetic patients commonly suffering from slow wound healing; diabetic foot ulcers are particularly difficult to manage. Relevant pharmaceuticals in the treatment of this condition command a global market worth of about US\$3 billion. In the US, Regranex is the only FDA approved diabetic foot ulcer wound healing medication, and being a protein product it is expensive (more than US\$600 a 15 g tube) and has to be stored at 4°C.</p> <p>WH-1 is currently under investigation in a Phase II clinical study in the treatment of Wagner grade 1 foot ulcers in diabetic patients. In order to further explore the wound healing efficacy of WH-1 in clinical applications, a randomized control study for grade 3 foot ulcers in diabetic patients will be performed. Worldwide patents of WH-1 have already been filed.</p> <p><b>The market prospects and the advantage of WH-1</b></p> |

Foot ulcers are the most frequent cause of diabetes-related hospitalization. Diabetes is now the top cause of non-traumatic leg amputations in the developed world. Thus, diabetic foot ulcers and related infections result in long-term disabilities for patients with the condition and subsequent high demands on the healthcare system.

Today's ageing population is also a key driver of the advanced wound management market as the elderly account for a significant portion of chronic wound-related cases. Overall, the global advanced wound care management market is about US\$5 to 7 billion with steady annual market growth of around 8.3%.

In comparison to Regranex, WH-1 has similar wound healing efficacy, and being an extract of botanical material, has considerable prior human use experience. It is cost effective to manufacture (less than US\$2 for a 15g tube) and has a stable storage profile. In addition to accelerating tissue regeneration for wound closure, WH-1 also has antiseptic and anti-inflammatory properties. With these benefits, WH-1 can be considered a promising candidate for the treatment of diabetic-induced foot ulceration, burn healing and bed sore ulceration.

**Patent status and no.**

Worldwide patents of WH-1 have been filed: Taiwan (No. 094145941), United States (11/605,178; 11/847,220), European Union (06024463.9; 07118802.3), Japan (2007-211943), South Korea (2007-0123636), Malaysia (PI-20072012), India (1556/KOL/2007), and China.

**Type of business relationship sought:**

Licensing or partnering.

**Licensing contact**

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