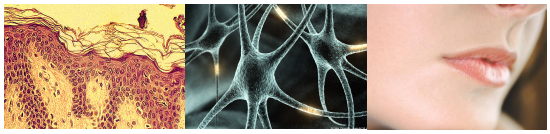


GALLIXA® (topical gallium maltolate)
Executive Summary

MAJOR TARGET MARKET
- Peripheral neuropathic pain
  - >10 million people in U.S. >100 million people worldwide
  - Current therapies are unsatisfactory
  - >$1.5 billion U.S. market

OTHER POTENTIAL MARKETS
- Arthritis
- Back pain
- Tendinitis
- Other chronic pain

COMPETITIVE ADVANTAGES
- Patent-protected technology
- Increased efficacy
- Increased safety
- Low manufacturing cost
- Potent anti-inflammatory agent
- Demonstrated anecdotal efficacy in severe, recalcitrant chronic pain
- Published case study
- Published pilot clinical trial
- Intravenous form of gallium already FDA-approved
- Large amount of safety data on oral form from clinical trials
- Clinical testing of topical product is relatively fast, simple, and low-cost
- GALLIXA trademark has been registered

OVERVIEW

Safe and effective treatment for chronic pain is probably the ***largest unmet medical need in the world***, with chronic pain afflicting more than 100 million people in the United States alone. GALLIXA® is a topical formulation of gallium maltolate, a novel compound with potent anti-inflammatory and analgesic activity. It has demonstrated remarkable anecdotal clinical efficacy in the treatment of pain, including many types of chronic pain, with no observed adverse effects. ***GALLIXA® is intended to become the preferred first-line topical therapy for much chronic pain***, including difficult-to-treat peripheral neuropathic pain.

PROBLEMS ADDRESSED

Initially, GALLIXA® will be targeted to peripheral neuropathic pain (PNP), which afflicts more than ten million adults in the U.S. and more than 100 million worldwide. This type of pain, which results from damage to nerves, is usually chronic, and is commonly so severe as to be disabling. PNP occurs frequently in those with diabetes, cancer, infections, inflammation, and injuries.

- An estimated 20-25% of diabetics have a type of PNP called painful diabetic neuropathy.
- Postherpetic neuralgia (PNP that persists after an episode of shingles) strikes at least 800,000 Americans per year.
- About a third of cancer patients experience PNP, including about half of breast cancer patients who had surgery.
- PNP following other surgery is common, and is also common following traumatic injury.

Current treatments for PNP are of limited efficacy and often cause significant adverse side effects. Many patients with PNP find little to no pain relief from any available therapeutic product.

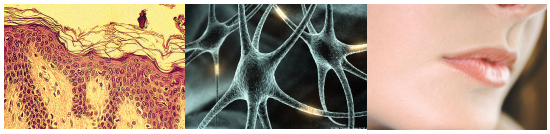
THE GALLIXA® SOLUTION

GALLIXA® is a topical form of gallium, a metal that has shown activity against inflammation. Gallium is a particularly exciting new therapeutic because it naturally targets pathologic tissue while sparing healthy tissues.

An intravenous gallium formulation (gallium nitrate) *has already been approved by the FDA* (for cancer-related hypercalcemia), and has demonstrated clinical efficacy in several types of cancer. Gallium nitrate is not, however, well suited for topical or oral administration. Gallium maltolate—a complex of gallium with maltol—was developed specifically for topical and oral administration. Maltol occurs naturally in many foods, including some fruits and many baked goods, and is a common FDA-approved food additive.

Orally administered gallium maltolate has successfully completed Phase I clinical trials in healthy volunteers and in some advanced cancer patients. No dose-limiting toxicity has been observed at daily doses of up to 3.5 grams per day for repeated 28-day periods. In animal experiments, oral gallium maltolate has demonstrated strong anti-inflammatory activity in models of rheumatoid arthritis.

Topically administered gallium maltolate has shown potent activity in anecdotal cases of postherpetic neuralgia, trigeminal neuralgia, painful diabetic neuropathy, inflammatory arthritis, and other painful conditions—with no observed adverse effects. Pain relief often occurs within minutes of administration, even when all previous therapies have failed. A published case study and pilot clinical trial indicated efficacy and safety. ***Topical doses are about one-thousandth of the oral doses that have appeared safe in clinical trials.***



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INTELLECTUAL PROPERTY

GALLIXA® is patent-protected in the U.S. and in some other major countries. U.S. patents include 9,114,067, 8,871,246, 8,506,990, 8,293,268, 8,168,214, and 5,747,482. Patent applications have been submitted for additional compositions and methods-of-use, including additional methods of treating pain. All patents and patent applications are owned and controlled by the inventor, Dr. Lawrence R. Bernstein.

DEVELOPMENT PLAN FOR THE NEXT TWO YEARS

Seven million dollars is being sought to fund the development of GALLIXA® through proof-of-concept Phase I/II clinical trials to demonstrate efficacy and safety in patients with chronic peripheral neuropathic pain. Two initial, parallel trials are planned: in postherpetic neuralgia and in trigeminal neuralgia. These initial trials would enroll about 100 to 150 patients each, and would last several months. The $7 million would cover the costs of the trials themselves ($3 million), plus drug manufacture and formulation ($800,000), animal research that may be required ($1,200,000), patent expenses ($400,000), personnel/consultants ($1,000,000), and rent, insurance, legal, and travel costs ($600,000). ***Efficacy would likely be determined within a few months. The requested funding may be sufficient to take the product through FDA approval.***

THE CURRENT OPPORTUNITY

GALLIXA® (topical gallium maltolate) can enter Phase I/II trials in patients with peripheral neuropathic pain. The topical formulation may be considered a new dosage form of gallium, a product already approved by the FDA (gallium nitrate for injection). Approval of the topical product in peripheral neuropathic pain could be relatively fast, due to (1) the simplicity and rapidity of clinical testing in this indication, (2) the unmet medical needs addressed, and (3) the extremely low, localized dose used (less than one-thousandth the highest apparently safe oral dose). An over-the-counter designation could be contemplated. ***Clinical trials on topical gallium maltolate will be facilitated by Gallixa LLC already owning and controlling all the preclinical and clinical data regarding oral gallium maltolate.***

Although peripheral neuropathic pain would likely be the first indication for which FDA approval would be sought, GALLIXA® has also demonstrated anecdotal efficacy in many other types of pain, including pain associated with arthritis, tendinitis, burns, insect bites, injuries, and other conditions. In addition, GALLIXA® has shown anecdotal efficacy in treating inflammatory skin conditions, such as psoriasis, acne, eczema, actinic keratosis (pre-cancerous skin lesions), and many others. The market for neuropathic pain treatment is at least $1.5 billion in the U.S. alone, with the market for the topical treatment of other pain and skin conditions several times larger.

GALLIXA® will be developed either through the existing company, Gallixa LLC, or through partnering with an established pharmaceutical company that has the ability to develop the product. Licensing in particular geographical regions is also possible. If you are interested in any of these options, please contact:

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Additional information can be found at https://www.gallixa.com/AboutGallixa.html