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Vapogenix Reports Encouraging Phase II Results of Topical Non-Opioid Pain Medication

- Data reveal VPX638 significantly reduces pain and use of opioids
- Company anticipates NDA filing in the U.S. by 2022

Houston, TX (October 29, 2019) — Vapogenix, a clinical-stage company developing a new class of topical non-opioid, lidocaine-free analgesics, today announced results of a Phase II clinical trial of its lead product, VPX638, which demonstrate rapid onset and sustained duration of pain relief and reduced opioid use for patients with painful wounds.

Analysis revealed that the patients experienced a significant decrease in pain for 8, 12 and even 24 hours after receiving VPX638. The trial, which was conducted in Australia, did not achieve its primary endpoint, most likely due to study design issues. However, in addition to the sustained reduction in pain, there was a substantial decrease in opioid use among the patients and no evidence of systemic or local adverse side effects.

"The data strongly suggests that this novel class of non-opioid analgesics has the potential to provide substantial pain relief for patients with all types of wounds, including diabetic foot ulcers and venous ulcers, burns and non-healing traumatic and post-surgical wounds," said Vapogenix CEO Heather Giles, Ph.D.

"The national opioid epidemic combined with the continuing clinical need for pain relief creates an urgent demand for Vapogenix's pipeline of non-opioid analgesics," Giles added. "There is a compelling need for new pain medications that are opioid sparing and are safe with no systemic side effects."

In the Phase II trial, 50% fewer VPX638 patients required opioids for the 24 hours post-drug application. The number of opioid free patients in that 24 hour period was 31% higher than in the control group, and there were no observed systemic side effects among patients who received VPX638. In addition, patients receiving the medication experienced a decrease in opioid use during the night, suggesting a reduction in sleep interruption.

"The overall positive data coupled with the need for non-opioid pain medicines clearly warrant further study and development of VPX638," said Prof. Michael Woodward, M.D., of the

University of Melbourne and Past President of the Australian Wound Management Association. "Wound pain is a huge problem and to have an analgesic that can reduce the need for narcotic prescriptions would be a true breakthrough."

Pat Aldons, MBBS, FRACP, Senior Visiting Consultant Physician at The Prince Charles Hospital in Brisbane, added, "Pain is often the worst symptom associated with wounds and it can delay a patient's recovery. A topical analgesic with a long duration of action would be a really significant advance."

Giles said the encouraging data from the Phase II trial of VPX638 will inform the design of Phase IIb/III studies expected to begin in 2020 followed by a new drug application (NDA) filing with the U.S. Food and Drug Administration in 2022.

Vapogenix's portfolio of topical analgesics are novel, patented formulations of volatile anesthetics (VAs), which are currently unformulated and approved for use by inhalation for general anesthesia.

The company has formulated these VAs into topical gels and emulsions for localized treatment of pain associated not only with wounds, but also combat-related injuries, inflammatory conditions, and pain associated with common medical procedures, such as needle injections and more invasive procedures involving needle biopsies and cosmetic dermatology. For children, ineffective procedural pain management is a serious problem and can have long-term negative effects. In addition, Vapogenix's topical analgesics have anti-inflammatory and anti-microbial properties.

Vapogenix also announced it has retained Lighthouse BioPartners LLC (<u>https://www.lighthousebiopartners.com/</u>) to explore financing and strategic partnering opportunities to further develop Vapogenix' proprietary pipeline of non-opioid medications.

About Vapogenix:

Vapogenix, based in Houston, TX, is a clinical stage company developing a new class of topical, non-opioid analgesics to alleviate pain. While most pain is localized, most pain medications are administered orally, which often results in systemic side effects. Vapogenix is focused on treating pain locally – at its source. The Company's products are volatile anesthetics (VAs) formulated for topical application. VAs currently are unformulated and approved for use only as general anesthetics. Vapogenix has a robust intellectual property portfolio with 34 issued or allowed patents globally. To learn more about Vapogenix, visit <u>www.vapogenix.com</u>.

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