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CHX Technologies retains TPIreg (Hamilton, ON) as its strategic regulatory advisor in preparing Prevora's new drug application to the US FDA

CHX Technologies has engaged TPIreg, an experienced pharmaceutical regulatory team in Hamilton, Ontario, to assist in the preparation of a new drug application for CHX's topical drug, Prevora, to the US Food and Drug Administration.

Prevora is approved by Health Canada, the European Medicines Agency and by the British and Irish regulatory authorities for the prevention of dental decay in high risk adults.

The FDA application for Prevora is planned for 2017. Prevora's application will be for a first-in-class therapeutic indication.

About Prevora: This is a clear, prescription tooth coating painlessly applied by a dental professional to the teeth of adults who are experiencing cavities, crowns, root canals or extractions or who are at high risk of this medical condition. Prevora works to manage the bacteria which cause dental decay. It is one of the most independently-reviewed preventive dental products, having been evaluated in 4 randomized controlled studies involving adolescents, new mothers and adults from ages 18 to 80. In its pivotal Phase III clinical trial for the FDA, Prevora reduced cavities by up to 70% in the highest risk adults over one year, versus placebo.

About dental decay in adults: About 1 in 3 adults past mid-life experience recurrent cavities and another 1 in 3 are at high risk of this most common chronic disease. Adults suffering from a high rate of dental decay include diabetics and those taking multiple medications for arthritis, mood disorders, high blood pressure, Parkinson's disease, or other chronic disorders. Existing surgical treatments for cavities (e.g. fillings and crowns) do not manage the bacteria causing these problems. Dental surgery is, thereby, inherently far more expensive than Prevora. 1 in 4 American adults report they need to see a dentist but cannot afford to do so.

About CHX Technologies: CHX is a specialty pharmaceutical company with a vision to improve the affordability of good oral health. CHX recently announced a strategic partnership with MCI Medical Clinics in Canada to co-market Prevora as a new medical service available from the family doctor.

About TPIreg: TPI is an established regulatory consultancy advising pharmaceutical companies in North America and the EU.

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