



## NEWS RELEASE

### **For Further Information Contact:**

Erik Danielsen  
Nymox Pharmaceutical Corporation  
1-800-93NYMOX  
[www.nymox.com](http://www.nymox.com)

### **For Immediate Release:**

#### **Nymox Provides Update on Regulatory Filing Activities**

HASBROUCK HEIGHTS, NJ (November 16, 2020) Nymox Pharmaceutical Corporation (NASDAQ: NYMX) is pleased to provide a current update on the regulatory filing status for Fexapotide Triflutate (FT), Nymox's first in class lead product for the treatment of benign prostatic hyperplasia (BPH). Substantial progress has been made and there are no material changes to the content of the planned applications.

Unavoidable delays have been incurred in this project mainly due to the very long-term data, the standard requirements for updating various aspects of the filing, dependence on external vendors, and the general inefficiencies due to the Covid situation. Nevertheless, the Company is highly confident that the filings will occur in the near-term horizon, although this will likely be in first quarter, and not fourth quarter 2020.

Dr Paul Averback, CEO said, "Fundamentally we are very pleased with the progress and the overall quality of the work going into our filings. We are as impatient as our shareholders but we are very confident that we will complete these important milestones in the near future. Our Fexapotide product is first in class, and has strong supportive long-term data. There is a large unmet need for a safe injectable with better efficacy than current medications and without the bothersome side effects of conventional drug treatments. The filings will occur as soon as possible but we cannot compromise on the quality for this ground-breaking treatment, and so we must ask again for patience from our valued supporters."

Dr. Averback added, "We provide this update today to reassure our stakeholders that the Company is essentially on track and in the final stages of completing our NDA submission. The majority of the labor-intensive data updating and preparation for the chemistry, manufacturing and controls; the non-clinical scientific work, the safety studies, and the clinical modules have been accomplished. There remains some very important final writing steps to be completed, and we will continue to keep our shareholders up to date on the final stages of the filing documentation completion."

The company also reported that Nymox management have personally invested USD \$510,000 in direct placements in the Company's shares in the past 3 months.

The Company further announced that an additional 9 international patents have been issued for FT for the treatment of BPH and prostate cancer since the last update, providing increasing coverage for the Company's lead product.

Fexapotide (FT) has been designed and targeted for middle aged and elderly men throughout the world, who as they get older, develop enlarged prostate glands (BPH). Men with BPH often have progressive difficulties with urination and related symptoms that have serious impact upon their lives, causing discomfort, restricting activities, disrupting sleep, and leading to serious

complications. With advancing age, a majority of men will have some degree of prostate enlargement, often with the resulting distressing urinary tract symptoms. Many men end up needing invasive surgery which can have long-term side effects such as permanent retrograde ejaculation and other risks.

FT has shown long-term effectiveness for BPH without the distressing side effects often unavoidable with the available drugs and procedures. The results from the main U.S. multi-center randomized prospective blinded long-term studies of FT for BPH have been published in prestigious peer review journals including *World Journal of Urology* 2018 36: 801-809 (Fexapotide triflutate: results of long-term safety and efficacy trials of a novel injectable therapy for symptomatic prostate enlargement authored by Neal Shore, Myrtle Beach, SC; Ronald Tutrone, Baltimore, MD; Mitchell Efros, Garden City, NY; Mohamed Bidair, San Diego, CA; Barton Wachs, Long Beach, CA; Susan Kalota, Tucson, AZ; Sheldon Freedman, Las Vegas, NV; James Bailen, Louisville, KY; Richard Levin, Towson, MD; Stephen Richardson, Salt Lake City, UT; Jed Kaminetsky, New York, NY; Jeffrey Snyder, Denver, CO; Barry Shepard, Garden City, NY; Kenneth Goldberg, Lewisville, TX); Alan Hay, Salem, OR; Steven Gange, Salt Lake City, UT; Ivan Grunberger, Brooklyn, NY (<https://doi.org/10.1007/s00345-018-2185-y>) and *Therapeutic Advances in Urology* 2019, Vol. 11: 1–16 (Efficacy and safety of fexapotide triflutate in outpatient medical treatment of male lower urinary tract symptoms associated with benign prostatic hyperplasia authored by Neal Shore, Ronald Tutrone and Claus G. Roehrborn (<https://journals.sagepub.com/doi/10.1177/1756287218820807>)). Scientific studies were published recently in the highly regarded *Research and Reports in Urology* (2019 11:343-350) (<https://doi.org/10.2147/RRU.S231334>).

FT has also shown effectiveness in slowing the progression of low grade early prostate cancer. Results from the large multi-center prospective long-term FT prostate cancer study were published in the peer review literature in the prestigious *World Journal Of Urology* 2020 in the report Prospective Evaluation of Fexapotide Triflutate Injection Treatment of Grade Group 1 Prostate Cancer: Four Year Results authored by Neal Shore, Myrtle Beach, SC; Steven A. Kaplan, New York, NY; Ronald Tutrone, Baltimore, MD; Richard Levin, Towson, MD; James Bailen, Louisville, KY; Alan Hay, Salem, OR; Susan Kalota, Tucson, AZ; Mohamed Bidair, San Diego, CA; Sheldon Freedman, Las Vegas, NV; Kenneth Goldberg, Lewisville, TX; Frederick Snoy, Albuquerque, NM; Jonathan I. Epstein, Baltimore, MD. The FT prostate cancer article is available online at <https://doi.org/10.1007/s00345-020-03127-w>.

The FT prostate cancer study enrolled 147 men with localized Gleason Grade 6 T1c prostate cancer at 28 U.S. clinical investigation sites. Patients were followed with clinical and laboratory evaluations and regular periodic prostate biopsies for up to 5 years. Important clinical highlights from the study include: FT treatment reduced cancer progression (-67.7%) compared to controls (3 years, FT 15mg,  $p < .02$ , pooled FT  $p = .0265$ ) and also reduced (-54.7%) the incidence of surgery, radiotherapy or chemotherapy (4 years, FT 15mg  $p < .02$ ; pooled FT  $p = .0374$ ). At 4 years the incidence of surgery, radiotherapy or chemotherapy with increased Gleason grade was significantly reduced (FT 15mg -73.3%  $p = .0059$ , pooled FT  $p = .0064$ ). Results for the high dose (FT 15mg) were superior to the lower dose (FT 2.5mg). Safety data showed no serious adverse events related to FT during the study.

For more information please contact [info@nymox.com](mailto:info@nymox.com) or [800-936-9669](tel:800-936-9669).

#### Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Nymox, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding the need for new options to treat BPH and prostate cancer, the potential of Fexapotide to treat BPH and prostate cancer and the estimated timing of further developments for Fexapotide. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development program, future results, performance or achievements

to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of Nymox's regulatory filings, Nymox's substantial dependence on Fexapotide, Nymox's commercialization plans and efforts and other matters that could affect the availability or commercial potential of Fexapotide. Nymox undertakes no obligation to update or revise any forward looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Nymox in general, see Nymox's current and future reports filed with the U.S. Securities and Exchange Commission, including its Annual Report on Form 20-F for the year ended December 31, 2019, and its Quarterly Reports.