



## NEWS RELEASE

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### **For Immediate Release:**

## **Nymox Announces New Peer Review Publication of Prostate Cancer Fexapotide Clinical Trial Results in World Journal of Urology**

HASBROUCK HEIGHTS, NJ (February 24, 2020) Nymox Pharmaceutical Corporation (NASDAQ: NYMX) is pleased to announce that a new peer review report was published today in the World Journal of Urology, documenting the successful long-term clinical trial results after Fexapotide Triflutate treatment for early stage prostate cancer.

This report represents the first publication in the medical literature of multi-year long-term data from a well-powered prospective randomized multi-center clinical trial for a prostate injectable treatment in men targeted to low grade early prostate cancer and showing statistically significant efficacy for a locally targeted molecular injectable treatment.

The new publication is entitled "Prospective Evaluation of Fexapotide Triflutate Injection Treatment of Grade Group 1 Prostate Cancer: Four Year Results". The authors are 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 article is available online at <https://link.springer.com/article/10.1007/s00345-020-03127-w>.

The Fexapotide (FT) study was started in 2012 and 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. Patients randomized to FT were treated with a single one-time targeted injection of FT, either 2.5mg or 15mg. Statistical comparisons were made over time of the proportions of subjects and untreated controls who progressed to higher Gleason grade and/or invasive treatments instituted with prostatectomy, radiotherapy, or chemotherapy. 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.

The current recommended standard of care for these patients is active surveillance: patients are monitored carefully over time to determine if and when the cancer becomes more advanced and thus will require more aggressive treatment, like radiation therapy or surgery.

Dr. Neal Shore, lead author of the report, said "The study results demonstrate data in a large multi-center clinical trial of men treated with transrectal ultrasound guided FT for early stage, low risk prostate cancers, which suggest an effective result for reducing histopathologic progression, as evidenced by repeated biopsies over time, while also demonstrating a favorable safety profile. This study presents long-term FT data which supports its efficacy for avoidance of biologic progression in an active surveillance prostate cancer population. A therapy to optimize the success of an active surveillance strategy is a welcomed advance for these patients."

Dr Steven Kaplan, Professor of Urology and Director of the Benign Urologic Diseases and The Men's Health Program at Icahn School of Medicine at Mount Sinai, New York, and a co-author of the report said, "This study reports the long-term data from a prospective study of an injectable for localized Grade Group 1 prostate cancer -- which is the first time this has been accomplished for a very common problem in men. Regulatory approval of Fexapotide Triflutate (FT) will be a very important treatment adjunct for countless men with this problem."

The FT treatments were administered in a urology office setting without anesthesia or sedation, consisting of a single relatively painless transrectal injection into the area of the prostate cancer. The percentage of patients with surgery or radiotherapy with Gleason grade progression was reduced by 73.3% in patients treated with a single injection of FT 15mg and by 62.6% in pooled (high and low dose FT groups combined) FT patients compared to controls.

Dr. Jonathan Epstein a co-author and researcher involved in the study, stated "Although more and more men are electing active surveillance for low grade prostate cancer, approximately 25-35% will show increased grade on follow-up biopsy which typically leads to definitive therapy. In this study, Fexapotide Triflutate decreased the risk of upgrading on follow-up biopsy enabling men to stay on active surveillance. Even if Fexapotide Triflutate enables men to stay on active surveillance longer before they eventually experience upgrading, there would be a significant benefit for men to delay the onset of side effects associated with therapy and in the interim enjoy a better quality of life. Future studies are needed to expand the criteria for study of Fexapotide Triflutate to include men with large volume Grade Group 1 disease and possibly men with low volume, low percent pattern 4 Grade Group 2 cancer. Identifying the ideal candidates for Fexapotide Triflutate also factoring in multiparametric MRI findings remains to be determined."

FT is a pro-apoptotic proprietary drug which promotes natural programmed cell death (apoptosis) in prostatic glandular cells which compose the prostate cancer. FT has been safely administered to men in clinical trials in the U.S. involving over 1700 patients and controls treated for BPH or prostate cancer. FT has completed Phase 3 studies for BPH and further studies of FT for prostate cancer are planned in the near future.

For further detailed information about the published study please refer to the new report online at the World Journal of Urology.

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, 2018, and its Quarterly Reports.