



## NEWS RELEASE

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**For Immediate Release:**

## **Nymox Reports Successful New NYMOZARFEX (TM) Long-Term Prostate Cancer Treatment Clinical Trial Results**

### **NYMOZARFEX 15 mg Minimal Treatment of Low Grade Prostate Cancer Leads to Significant Long-Term Reduction in Incidence of Associated Prostate Cancer Surgery and Radiotherapy**

IRVINE, CA (July 25, 2023) Nymox Pharmaceutical Corporation [OTC: NYMXF] (the "Company") is pleased to announce today important new long-term clinical trial results from the Company's 146 patient NX03-0040 NYMOZARFEX (TM) U.S. study for low grade localized prostate cancer. New long-term follow-up data from the prospective randomized clinical trial of NYMOZARFEX (TM) for low grade early prostate cancer has indicated that there is strong statistically significant benefit from the treatment compared to controls when all available patient outcomes were included from 18 months to as long as up to >10 years after treatment.

These additional 5 to 10-year data points add to the 5-year data that was published in the peer review World Journal of Urology in 2020 (World J Urol 38, 3101–3111 (2020). <https://doi.org/10.1007/s00345-020-03127-w>). All clinical trial sites that were still open were contacted for follow-up data on the prostate cancer status of all available patients. A full effort was made to reach all possible subjects. The outcome comparisons showed greatly reduced percentages of subjects treated with NYMOZARFEX (TM) who had progressed by either cancer grade worsening or by prostate cancer surgery, radiotherapy, or chemotherapy; and which remained overall strongly statistically significant compared to the study's randomized controls ( $p < .01$ ).

This unique and successful study is the world's first and only long-term prospective randomized controlled study of an intraprostatic molecular injectable treatment for low-grade localized prostate cancer to have been accomplished. The new data represents the longest term data available from this major study.

Study NX03-0040 was undertaken starting in 2012 at investigational sites across the U.S. with 146 men with the biopsy confirmed diagnosis of Grade Group 1 prostate cancer. NYMOZARFEX (TM) was administered by a single painless injection directly into the prostate in a relatively simple procedure requiring several minutes or less in an office setting without sedation or anesthesia, and guided by routine ultrasound. NYMOZARFEX (TM) was injected into the area of the prostate where the cancer was previously detected prior to enrollment in NX03-0040. The patients were then biopsied after 6 weeks and then every 18 months, along with serial PSA measurements and long-term follow-up.

All subjects with 18 months or more follow-up were compared with the inclusion of follow-up data from up to 10 years or more after a single injection of NYMOZARFEX (TM). For the patients where investigational sites were closed or where patients for unrelated reasons were no longer available, the last known status reports were included if they were 18 months or longer. For any subject with a worsening (increase) in grade of prostate cancer on biopsy; or with prostate cancer surgery, or radiotherapy or chemotherapy, they were included regardless of time after study treatment, and were counted in the calculation as treatment failures. The data shows that the number of patients with one focal injection of NYMOZARFEX (TM) 15 mg directed at the tumor had significantly less progression to more advanced cancer or to major cancer treatments, than the randomized control subjects followed in the study.

Dr. Paul Averback, CEO of Nymox said, "We are very excited about this major step forward for NYMOZARFEX (TM) which represents a first in class painless and well tolerated treatment approach for the very important condition of low grade localized prostate cancer. NYMOZARFEX (TM) treatment has shown persistent long-term benefit in this

large study, where there was statistically significant less progression of the cancer in men who received the drug injection. The Company will soon be taking steps for meetings with regulatory authorities concerning marketing goals for NYMOZARFEX (TM). There is a global unmet medical need for more effective low-grade prostate cancer treatments that produce minimal collateral tissue damage and undesirable risks and often permanent unintended sexual, urinary, and bowel function side effects."

Nymox CEO added, "We further emphasize that NYMOZARFEX (TM) has also been shown to be associated with a significant reduction in the incidence of new prostate cancer in men suffering from BPH (benign prostatic hyperplasia). That other evidence which was initially unexpected came from patients who received NYMOZARFEX (TM) for their BPH in Nymox's long-term studies of 977 men with BPH in the U.S. as part of Nymox's pivotal Phase 3 BPH clinical program. Both 1) the long-term data reported here today involving prospective planned treatment of biopsy established low grade localized cancers, and 2) the unexpected long-term prevention of new onset confirmed cancer in BPH patients reported previously, together indicate that NYMOZARFEX (TM) has shown significant efficacy in men for the treatment and prevention of prostate cancer, without the risks and undesirable side effects generally associated with treatment of these conditions."

Low grade localized prostate cancer (Gleason 3+3; T1c) is a very common treatment problem. The Nymox study reported today involves patients with initially Gleason grade 3+3 or lower. These patients are found to have these tumors by biopsy which is usually instituted after finding abnormalities in PSA levels, and/or after abnormal digital rectal examination of the prostate, and/or after the patient has experienced lower urinary tract symptoms or other changes. Low grade localized prostate cancer represents a therapeutic challenge. Because of its slow growth and low initial level of malignancy, urologists and patients can be reluctant to proceed to invasive surgical treatments or radiotherapy due to the unpleasant and often permanent side effects these treatments cause in the genitourinary tract, such as sexual functional issues and/or urinary issues. Eventually if and when the tumor progresses, invasive surgical and/or radiotherapeutic procedures become necessary, with greater risk due to the progression. Occasionally the tumors become highly malignant after variable lengths of time. These risks cause understandable anxieties and distress and many men prefer to advance to invasive therapy before running these risks of higher grade cancers. It is widely acknowledged that a treatment like NYMOZARFEX (TM) that can destroy or ablate the low grade cancers of the prostate without the dreaded side effects and morbidities, would be an important benefit for these patients.

Prostate cancer is the most commonly diagnosed cancer in men, other than skin cancer, and is the second leading cause of cancer death for men. Approximately 50% of prostate cancers are initially considered low risk. One of the major problems with the main current prostate treatments for localized prostate cancer (radical prostatectomy, external beam radiation, brachytherapy) is the relatively high incidence of serious sexual and other problems post-treatment. In 9 studies, NYMOZARFEX (TM) treatment has been shown to have a negligible significant adverse effect profile post-treatment and no significant adverse effects on sexual or other functions or testosterone levels.

Leading urologists have long recognized the unmet need for prostate cancer treatments that can contribute to improved outcomes for their patients together with reduced side effects and stresses that may have significantly impact on quality of life. The goal of NYMOZARFEX (TM) injectable is to allow for an initial and less toxic treatment for low-risk prostate cancer patients, achieving the benefits of molecular ablation with minimal risk of side effects. For many patients, this treatment combined with surveillance would be extremely helpful for the unpleasant and persistent uncertainties, anxieties, and psychological/emotional burdens associated with only selecting active surveillance.

### **About NYMOZARFEX (TM) (Fexapotide)**

NYMOZARFEX (TM) is given in an in-office procedure that is administered in a few minutes without need of anesthesia or analgesia. The drug has been tested in clinical trials involving overall more than 1750 patients with over 1600 injections administered including over 1200 Fexapotide administrations. Fexapotide has led to significant long-term improvements and has shown an excellent safety profile without the side effects normally associated with existing BPH treatments.

There is an important unmet need in the global middle aged and elderly male population for effective treatment for prostate enlargement (known as BPH, benign prostatic hyperplasia). BPH affects up to half the global male population after late middle age, and the vast majority of men have the condition when they reach their mid-70's and older. Current medical treatments are intended for life-long treatment but are hindered by intolerable side effects that many or most men experience, and they stop treatment usually in the first year or two. These side effects can

be sexual problems or a variety of other issues, some of which are more serious such as hypotension, depression, possible increased risk of prostate cancer, retrograde ejaculation, and many others. Surgical treatments are effective usually, but have the drawbacks of surgical pain, anesthesia, catheterizations, complications and other risks such as the frequent permanence of retrograde ejaculation, and occasional need for re-treatments.

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, 2022, and its Quarterly Reports.