



NEWS RELEASE

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For Immediate Release:

NYMOX Receives RTF letter from FDA

IRVINE, CA (May 23, 2022) Nymox Pharmaceutical Corporation (NASDAQ: NYMX) Nymox reports today that it has received a Refusal to File (“RTF”) letter from FDA on Friday May 20th at 2:48 pm EST, with regard to the Company’s New Drug Application (“NDA”) for Fexapotide Triflutate.

Nymox’s position is that clarifications remain to be resolved at a follow-up meeting and that some significant inconsistencies were involved.

The letter referred to a new outstanding issue of longer-term safety data and indicated that Nymox needed to have longer-term safety data in its NDA. Longer-term full safety data (as long as 6 years after a single low dose non-systemic injection given one time only) was not requested by the FDA in any previous pre-NDA communications.

The Company’s position is that

1. Fexapotide safety profile is superior to any other conventional BPH treatment.
2. Fexapotide is a local injection with no detectable drug outside of prostate in patients after treatment. For a single injection (ie, given only one time) low dose local administration treatment, typical human clinical safety data duration requirements for approvals are in the few months range or less. Animal testing requirements are generally 2 weeks.
3. The FDA agreed at the end of Phase 2 that for eventual approval one-year safety data after a single injection of fexapotide 2.5 mg was adequate for Phase 3 pivotal studies, for clinical safety duration requirements. In Nymox pivotal Phase 3 trials 0017 and 0018, this data was achieved, and 12-month full safety data was provided in the NDA.
4. The FDA provided detailed safety requests at the fexapotide pre-NDA meeting, which categorically did not include a longer-term clinical safety data request for fexapotide.
5. In addition, the NDA does include even longer-term (2-3 years) full safety data for fexapotide from n=344 subjects in Phase 3 Studies NX02-0020 and NX02-0022.
6. There is no evidence of any long-term adverse safety outcomes in the pivotal study data for fexapotide.

Nymox will continue to seek clarifications on the above and will report further material information when available.

For more information please contact info@nymox.com or 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, 2021 and its Quarterly Reports.