

# **Nymox Pharma doubles on phase 3 study result**

**Nymox Pharmaceuticals (NASDAQ: NYMX}** shares doubled in a day upon the news that their phase 3 extension trial for NX-1207 was successful.

Nymox, whose shareprice was decimated with a prior disappointing result, now appears to be in the ascendancy again on the release of this excellent news.

For Immediate Release:

**Nymox Pivotal Phase 3 NX-1207 BPH Extension Trial Successfully Meets Primary Endpoint. Company Plans to File For Regulatory Approvals For Fexapotide Triflutate (NX-1207) .**

HASBROUCK HEIGHTS, NJ (July 27, 2015) **Nymox Pharmaceutical Corp. {NASDAQ: NYMX}** announced today that the Company's U.S. long-term extension prospective double-blind Phase 3 BPH studies NX02-0017 and NX02-0018 of fexapotide triflutate (NX-1207) for BPH have successfully met the pre-specified primary endpoint of long-term symptomatic statistically significant benefit superior to placebo. Fexapotide showed an excellent safety profile with no evidence of drug-related short-term or long-term toxicity nor any significant related molecular side effects in the 2 studies (n=978) .

The Company now intends to meet with authorities and to proceed to file where possible in due course for regulatory approvals for fexapotide triflutate in various jurisdictions and territories.

The primary endpoint variable of the long-term study was improvement in the AUA BPH Symptom Score which was

statistically significant ( $p<.02$ ) in fexapotide-treated patients compared to placebo, at a median duration of 42 months (3.5 years) after a single double-blind injection treatment of fexapotide vs. saline placebo. In addition, responder analysis for the primary endpoint variable met the prespecified endpoint ( $p<.01$ ). All subjects from both studies with 2 years or more duration follow-up after a single painless injection were eligible, however all documented treatment failures of any duration in the studies from day 1 onward were also included in the data as treatment failures. Patients were followed double-blind up to 65 months (5.4 years) after a single injection.

**Highlights of the pivotal Phase 3 extension top-line results are summarized as follows:**

- Median duration of 3.5 years from a single injection treatment mean improvement of 5.3 points in AUA BPH Symptom Score. Statistically significant (mean  $p<.025$ ; median  $p<.02$ ) vs saline placebo injection.
- Mean improvement of 7.1 points in AUA BPH Symptom Score (primary endpoint variable) after median duration of 3.5 years in first-line BPH treatment of fexapotide treated subjects ( $p<.025$  vs placebo).
- Patient responder rate: Statistically significant higher proportion (64%) of long-term improved patients in AUA BPH Symptom Score (primary outcome variable) after a single injection in fexapotide treated subjects vs controls ( $p<.005$ ).
- Improvement of nocturia: Percentage of patients with stabilization or improvement of frequency of nocturia in fexapotide treatment superior to placebo ( $p<.03$ ).

The Company also reported on new Phase 3 data of lowered incidence of surgery in patients in Phase 3 studies NX02-0020

and NX02-0022.

Reduced incidence of surgery: Subjects in Phase 3 studies NX02-0020 and NX02-0022 with 1 or 2 injections of fexapotide had statistically significant reduction of BPH surgery within 24 months of fexapotide treatment (1.7% incidence of surgery in 2 years) (p<.02 vs placebo).

**In addition, the following advantages of the new drug are highlighted:**

- Safety profile highly superior to existing treatments. Minimal or no sexual, hormonal or cardiovascular or other debilitating side effects.
- Reduced cancer risk in Phase 2 data: U.S. Phase 2 data showing therapeutic effect of fexapotide on prostate cancer. Phase 2 data showed fexapotide treated low grade localized prostate cancer (Gleason 3+3 or less) had statistically significant less progression compared to controls. By comparison, some commonly used older approved BPH treatments have been linked to increased cancer risk.
- Enhanced compliance and patient convenience compared to oral medications. Fexapotide is given as a single painless office treatment injectable. Older approved oral medications generally involve daily pills intended for the rest of the patient's life.

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**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, the potential of NX-1207 to treat BPH and the estimated timing of further developments for NX-1207. 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 NX-1207, Nymox's commercialization plans and efforts and other matters that could affect the availability or commercial potential of NX-1207. 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, 2014, and its Quarterly Reports.