Merigolix (TU2670) Phase 2a Topline Results

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History-Making Innovator in Drug Discovery & Development

TiUMBio

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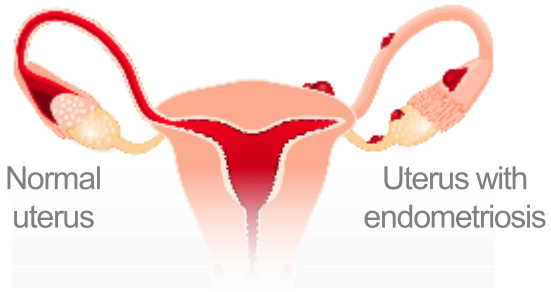
GnRH Antagonist-Driven Rapid Growth in the Endometriosis Market

Endometriosis

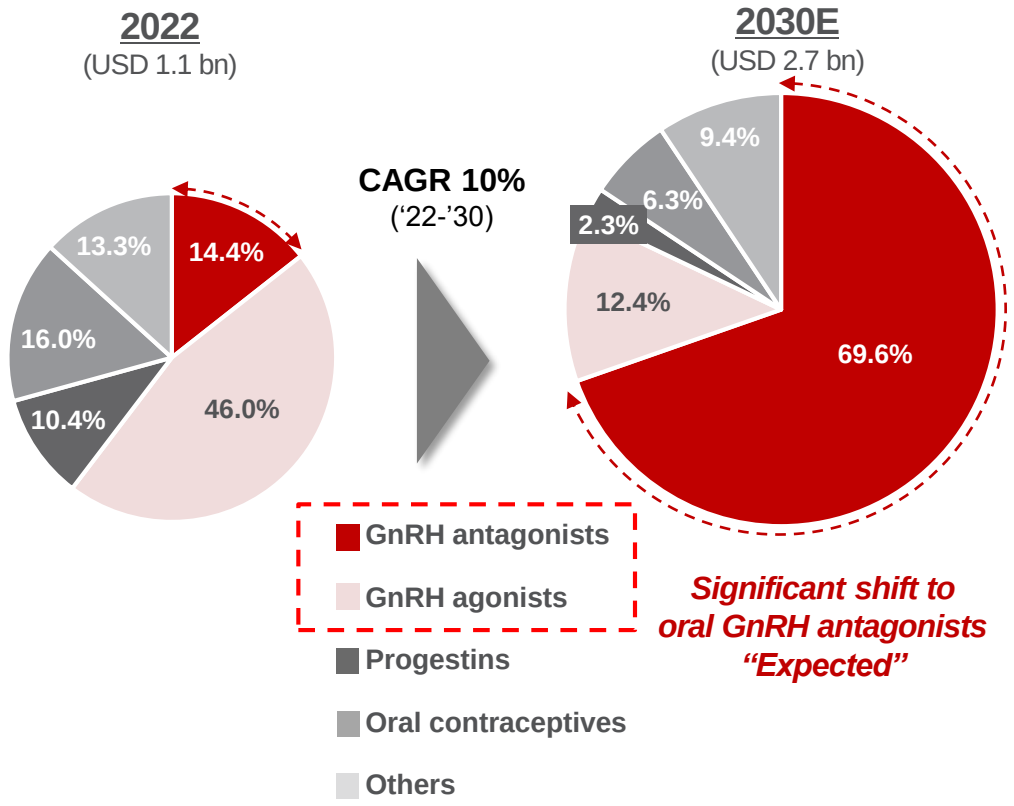


- Endometrial tissue growth outside the uterus and associated pelvic pain, dyspareunia, and infertility
- Prevalence rate is 10% - 30% of premenopausal women
- Global prevalent cases of diagnosed endometriosis in women aged 15–49 years are 196.2 million[1)]

1) Datamonitor Healthcare

Market Forecast

Endometriosis treatment across 7 major markets*



(Source: GlobalData)
* 7 major markets: United States, Germany, Italy, France, Spain, United Kingdom, Japan

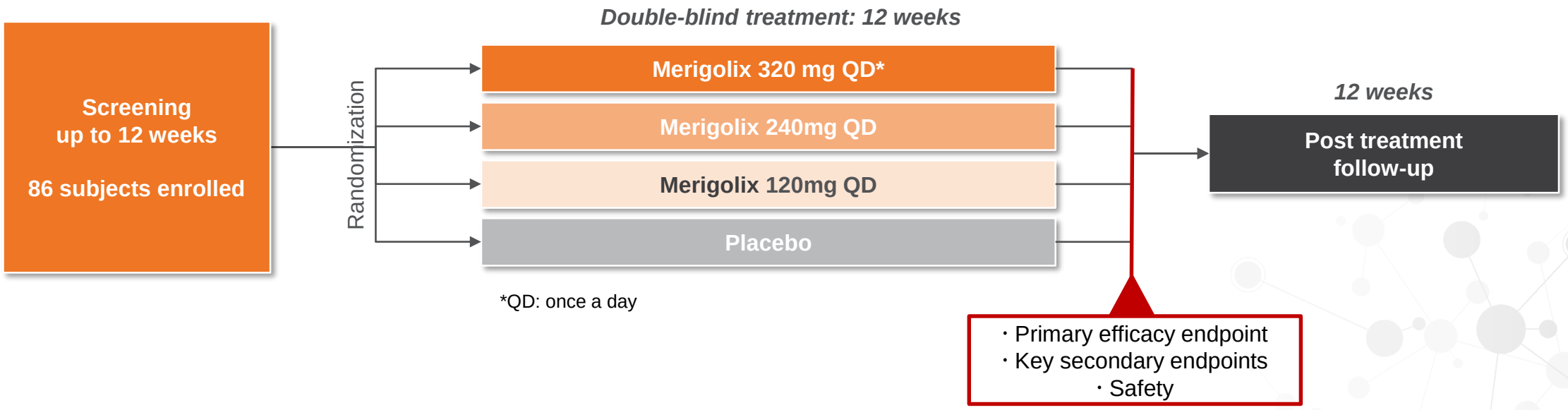
Phase 2a Study Design

Study title

A Phase IIa, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Proof of Concept Study to Evaluate the Efficacy and Safety of Orally Administered Merigolix (TU2670) in Subjects With Moderate to Severe Endometriosis-Associated Pain

Primary endpoint

Change from baseline to 12 weeks of treatment of the mean **Dysmenorrhea score** (defined as mean pelvic pain score on menstrual bleeding days) as measured by the Numeric Rating Scale (NRS)

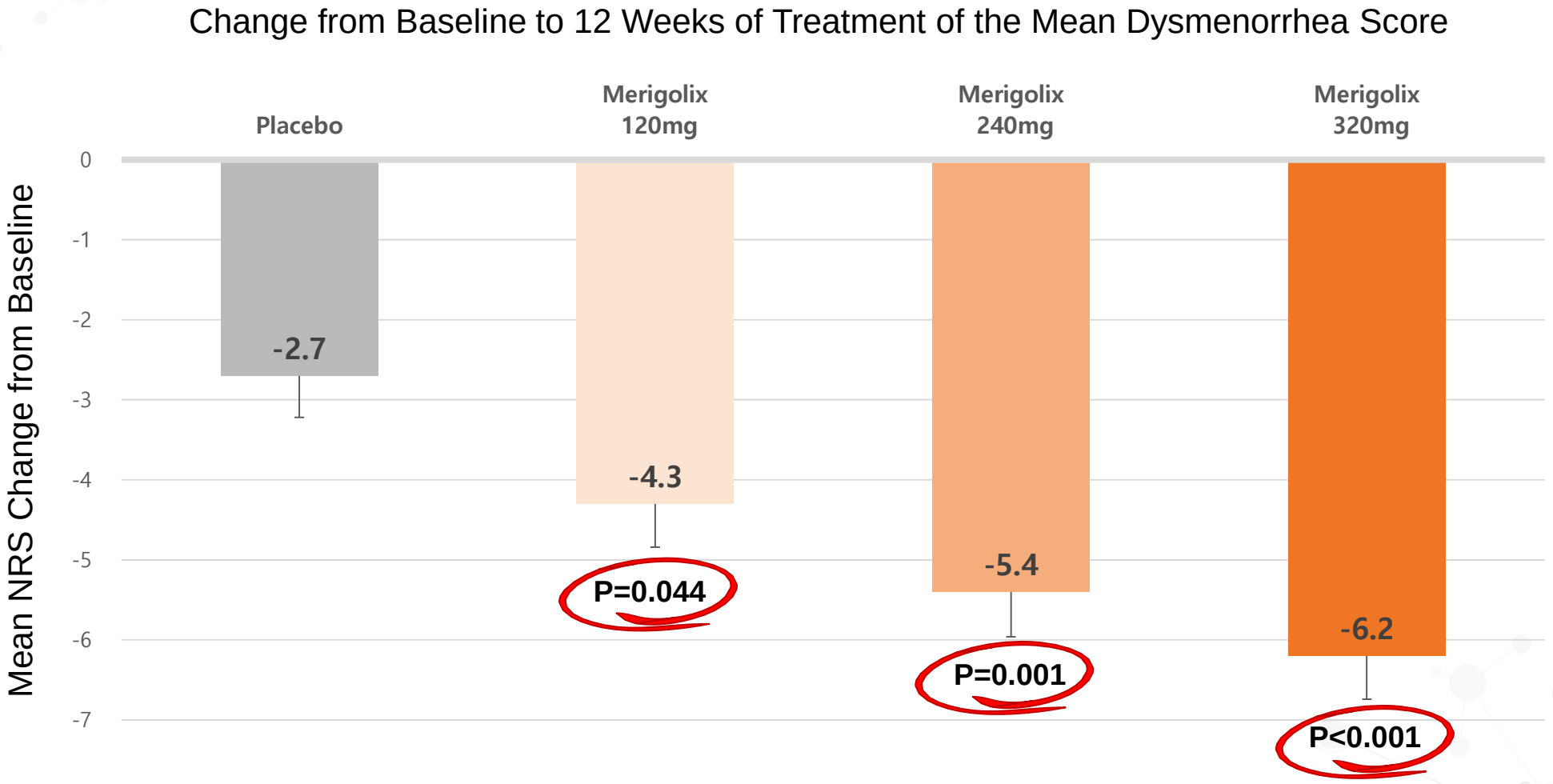


Baseline Demographics and Characteristics

		Placebo (N=22)	Merigolix 120mg (N=20)	Merigolix 240mg (N=20)	Merigolix 320mg (N=21)
Age mean years (SD)		33.8 (6.29)	33.5 (6.02)	36.0 (7.25)	33.5 (5.69)
Race	White	22 (100%)	20 (100%)	20 (100%)	21 (100%)
	Others	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Weight mean (Kg, SD)		64.13 (11.02)	65.68 (13.87)	68.98 (12.69)	64.53 (12.79)
BMI mean (Kg/m^2, SD)		23.18 (3.63)	23.43 (3.87)	25.10 (4.35)	23.39 (3.98)
Dysmenorrhea NRS score	Mean (SD)	6.4 (1.45)	7.3 (2.05)	6.7 (1.54)	6.3 (1.60)
Non-menstrual pelvic pain NRS score	Mean (SD)	4.8 (1.91)	5.4 (2.50)	5.0 (1.44)	4.4 (2.35)

N = full analysis set
SD = standard deviation
Dysmenorrhea: menstrual pain (월경통)
Non-menstrual pelvic pain (비월경 골반통증)

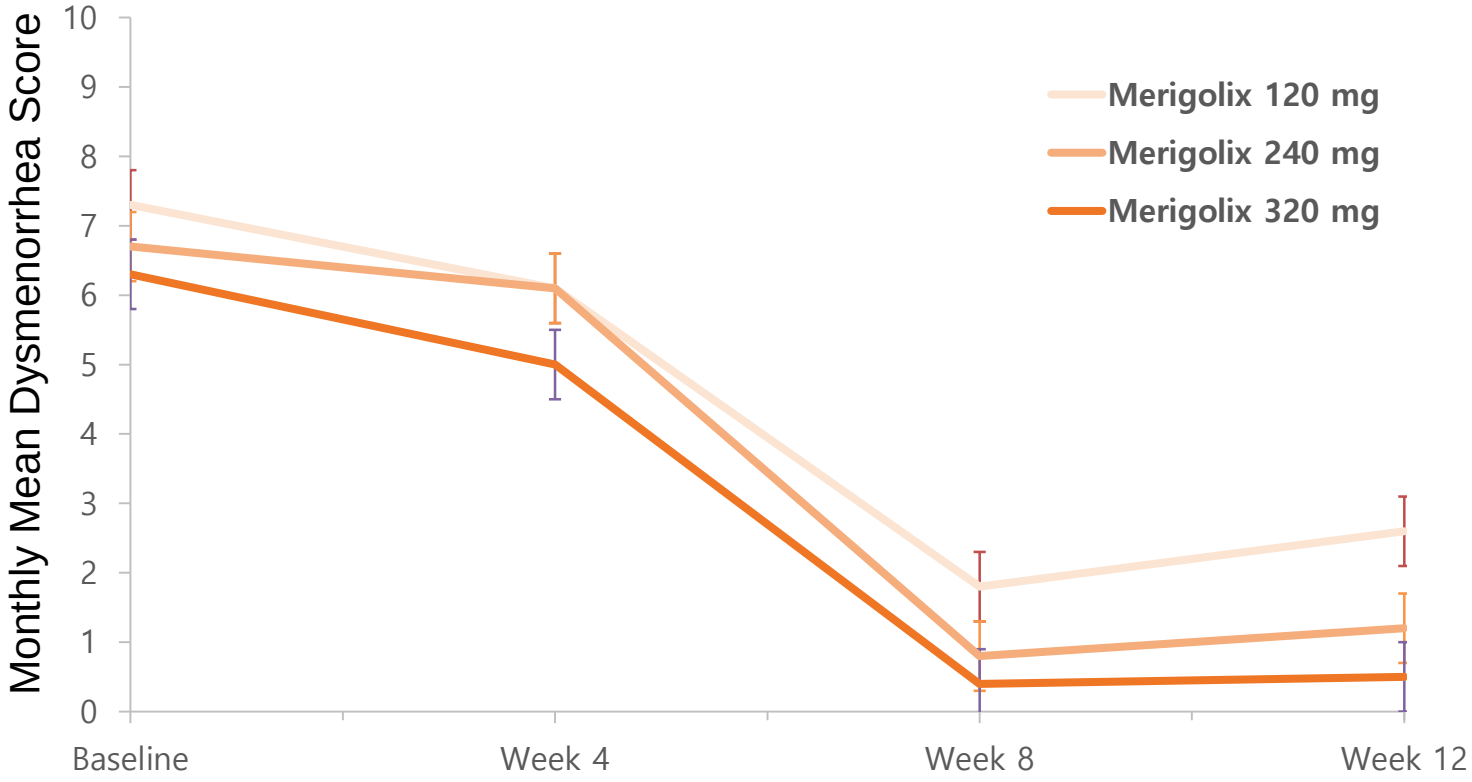
Primary Endpoint Achieved Across All Tested Doses

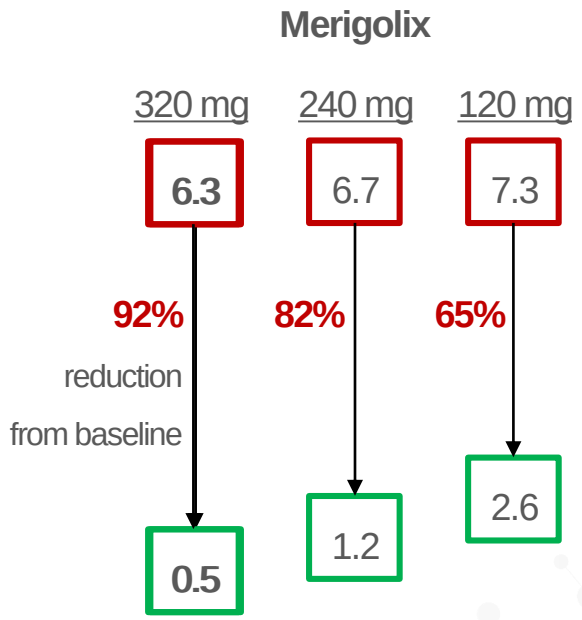


* Dysmenorrhea: menstrual pain (월경통)
** Pain assessed on Numerical Rating Scale: 0-10
*** Bars represent mean+/- standard error

indicates a statistically significant difference (p<0.05) compared to placebo

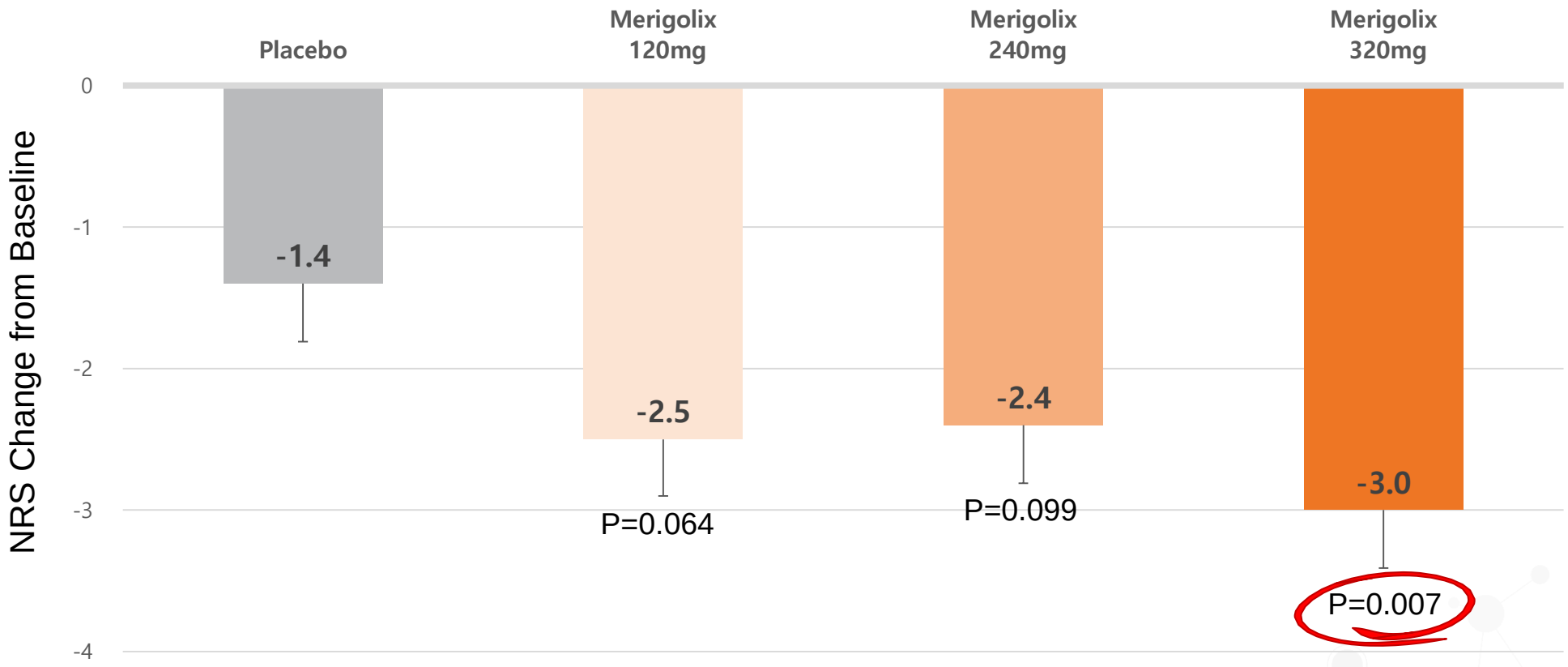
Merigolix Demonstrated Substantial Reductions in Dysmenorrhea





Key Secondary Endpoint of Non-Menstrual Pelvic Pain

Change from Baseline to 12 Weeks of Treatment of the Mean NRS Pain Score for Non-Menstrual Pelvic Pain (NMPP)



- In the 120 mg and 240 mg treatment groups, statistical significance ($p<0.0167$) can be achieved with 50 and 70 subjects, respectively, in a larger sample size model (approximately an additional 30 and 50 patients in each group)

* NPMM: Non-menstrual pelvic pain (비월경 골반통증)
** Bars represent mean+/- standard error

Other Secondary Endpoints

Secondary Endpoints		Placebo	Merigolix 120mg	Merigolix 240mg	Merigolix 320mg
Dyspareunia* NRS score	Mean change from baseline to Week 12	-1.2	-2.4	-2.7	-3.6
	p-value		0.104	0.045	0.002
Patient Global Impression of Change** (PGIC) from baseline to Week 12 (ranging 1 to 7)	p-value		0.086	0.049	0.006

* Dyspareunia (성교통)
** PGIC (자궁내막증 통증의 변화): 총 7개 기준(Very much better / Much better / A little better / No change / A little worse / Much worse / Very much worse)으로 통증 분류하여 측정

Summary of Adverse Events

Number (%) of Women	Placebo (N=23)	Merigolix 120mg (N=20)	Merigolix 240mg (N=21)	Merigolix 320mg (N=22)
At least one adverse event	12 (52.2%)	12 (60.0%)	14 (66.7%)	19 (86.4%)
TEAE* related to study medication	4 (17.4%)	7 (35.0%)	6 (28.6%)	11 (50.0%)
TEAE leading to discontinuation of study medication	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (4.5%)
Serious TEAE related to study medication	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Commonly occurring TEAEs (≥ 5%)				
Hot flush	0 (0.0%)	3 (15.0%)	2 (9.5%)	6 (27.3%)
Headache	2 (8.7%)	1 (5.0%)	2 (9.5%)	2 (9.1%)
Nausea	2 (8.7%)	1 (5.0%)	2 (9.5%)	2 (9.1%)

*TEAE: Treatment-emergent adverse events

Merigolix Phase 2a Clinical Trial Conclusions & Next Step

1. This study met its primary endpoint of change of dysmenorrhea (menstrual pain) score at all doses

- 320 mg QD **p<0.001**
- 240 mg QD **p=0.001**
- 120 mg QD **p=0.044**

→ **Remarkable reductions in dysmenorrhea** (**92%** and **65%** for 12 weeks of treatment) at high and low doses of merigolix represent that merigolix has the potential to become **best-in-class oral GnRH antagonist**

2. 320 mg of merigolix showed a significant reduction of Non-Menstrual Pelvic Pain (NMPP), a key secondary endpoint

And both 120 and 240 mg can achieve statistical significance in the statistical simulation model with increasing the number of patients

3. Merigolix is well tolerated and safe, consistent with previous clinical studies

4. Multi-dose options will be available for patients with varying symptoms

Next steps

- The clinical study report (CSR) with more detailed information and analysis is expected in Q3 2024
- The dosage levels for the next clinical trials will be determined after a thorough review

Merigolix Showed Better Therapeutic Profiles than Any Other GnRH Antagonists

		Merigolix		Elagolix				Relugolix + add-back therapy (ABT)	
Dose per day (regimen)		120 mg (once daily)	320 mg (once daily)	150 mg (once daily)		400 mg (200 mg twice daily)		40 mg + ABT[1] (once daily)	
Time frame		At 12 weeks		At 12 weeks				At 24 weeks	
Study		Phase 2a		Phase 3 EM-1	Phase 3 EM-2	Phase 3 EM-1	Phase 3 EM-2	Phase 3 Spirit 1	Phase 3 Spirit 2
Pain score reduction rate	Dysmenorrhea	**65%**	**92%**	47%	46%	80%	82%	73%	75%
	Non-menstrual pelvic pain	**54%**	**70%**	25%	33%	40%	44%	50%	49%
		Low dose	High dose	Low dose		High dose		Single dose	

1) Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg
* Source: public data
** No direct head to head data available - caution advised when comparing clinical studies with different assessment measures

Thank You

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