iPhase 11 clinical evaluation of the safety and effectiveness of Furitane (KX-826) in the treatment of androgenic hair (AGA) in adult men in China |Bed test (KX-826-CN-1002)

Zhang Jianzhong 1, Yang Qinsheng 2, Zhou Cheng 1, Wang Huiping 3, Ding Yangfeng 4, Yang Chen 5, Li Yumei 6, Yang Shulei7

1.Peking University People's Hospital, 2.Huashan Hospital Affiliated to Fudan University, 3.General Hospital of Tianjin Medical University, 4.Shanghai Hospital of Dermatology, 5.Hospital of Dermatology, Southern Medical University, 6.Jiangsu University Affiliated Hospital, 7.The First Hospital of Peking University

purpose |

:The purpose of this study is to evaluate the safety of Furitane (KX-826) in the treatment of Chinese adult male androgenic hair (AGA) volunteers, |Group drug exposure and effectiveness, and determine the recommended dose for Phase III trials.

method

• This study is a multicenter, randomized, dual-language, placebo-controlled phase 1 clinical trial (KX-826-CN-1002). • Chinese adult male AGA patients who meet the Hamilton-Norwood classification (Ivv, IV, V), in accordance with the ratio of 1:1:1:1 | Randomly assigned to KX-826 2.5mg (0.25% concentration) BID group, 5 mg (0.5% concentration) QD group, 5 mg (0.5% concentration) BID group and placebo group (QD group and BID group). • The study design and efficacy endpoints are shown in Figure 1.

Figure 1 Study design and efficacy endpoints

Abbreviations: QD, once a day; BID, twice a day.

result

◆ Patient baseline characteristics

• 120 cases of Chinese adult male AGA volunteers (average height: 172.95cm; average weight: 75.05 kg), randomly assigned to KX-826 2.5mg (0.25% concentration) BID group (n=30), 5 mg (0.5% concentration) QD group (n=30), 5 mg (0.5% concentration) BID (n=30) group, placebo QD group (n=10) and placebo BID group (n=20), detailed patients The baseline characteristics are shown in Table 1.

Table 1 Baseline characteristics of the faithful

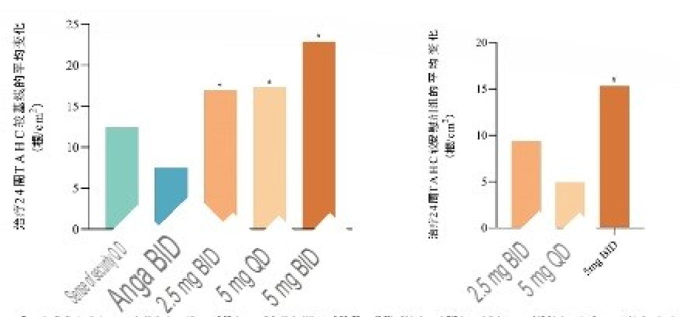
	Anti-wall agent QD (n-10)	anti-wall agent BID (n-20)	2.5 mg BID (n-30)	5 mg QD (n=30)	5 mg BID (n=30)	total (n=120)
Lunch age (years old), mean (SD)	37.0 (6.13)	34.2 (7.55)	36.9 (7.52)	34.4 (7.76)	36.1 (9.57)	35.6 (8.09)
Body mass index (kg/m2): mean (SD)	25.37 (4.51)	26.03 (3.15)	24-40 (2.08)	24.90 (2.45)	25.23 (3.40)	25.08 (2.96)
Han nationality, n (%)	10 (100.0)	18 (90.0)	30 (100.0)	30 (100.0)	29 (96.7)	117 (97.5)
AGA rating, n (%)						
II vertex	2 (20.0)	10 (50.0)	12 (40.0)	20 (66.7)	11 (36.7)	55 (45.8)
IV	2 (20.0)	4 (20.0)	12 (40.0)	8 (26.7)	11 (36.7)	37 (30.8)
V	6 (60.0)	6 (30.0)	6 (20.0)	2 (6.7)	8 (26.7)	28 (23.3)
Smoking history, n (%)						
Never smoke	7 (70.0)	13 (65.0)	20 (66.7)	22 (73.3)	21 (70.0)	83 (69.2)
Still smoking	3 (30.0)	7 (35.0)	9 (30.0)	7 (23.3)	8 (26.7)	34 (28.3)
Used to smoke	0	0	1 (3.3)	1 (3.3)	1 (3.3)	3 (2.5)

| Endings: SD, standard partial hall.

◆ Main efficacy endpoints

-The average change in TAHC from baseline for 24 weeks of treatment is shown in Figure 2.

Figure 2 The average change in TAHC in 24 weeks of treatment

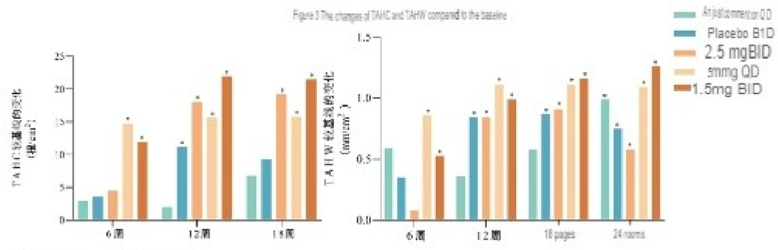


Remarks: *indicates that compared with the lowest line p < 0.05; * means "p" with An H item < 0.05, E5 mg (0.5% of this degree) BID has a daily increase of 15.34 shares/cm3 compared to the placebo.

◆ Secondary efficacy endpoints

• The changes in TAHC after 6, 12, and 18 weeks of treatment and TAHW compared to baseline after 6, 12, 18, and 24 weeks of treatment are shown in Figure 3.

Figure 3 The changes of TAHC and TAHW compared to the baseline



Note: *Indicates that compared with the baseline<0.05

• The self-assessment of HGA subjects, the evaluation of researchers and the evaluation of third-party professional doctors are shown in Table 2.

Table 2 HGA Evaluation

Treatment efficency	Security agent QD	Amway BID	2.5 mg BID	.5 mg QD	5 mg BID
W6D1(n)	10	19	28	30	30
Subject self-assessment (n2%%)	6 (60.00)	9 (47.37)	9 (32.14)	16 (53.33)	17 (56.67)
Researcher evaluation (n,%%)	7 (70.00)	8 (42.11)	12 (42.86)	16 (53.33)	18 (60.00)
Evaluation by a third-party professional doctor (n, 56)	1 (10.00)	1 (5.26)	4 (14.81)ª	7 (23.33)	5 (16.67)
W12D1 (n)	10	17	26	30	29
Subjects do not understand my assessment (n, 3%)	6 (60.00)	10 (58.82)	14 (53.85)	21 (70.00)	20 (68.97)
Researcher evaluation (n2%%)	6 (60.00).	10 (58.82)	15 (57.69)	19 (63.33)	20 (68.97)
Evaluation by a third-party professional doctor (n, 5%)	2 (20.00)	4 (23.53).	10 (38.46)	10 (33.33)	13 (44.83)
W18D1 (n)	10	17	26	29	29
Subject self-assessment (n2%6)	6 (60.00)	13 (76.47)	19 (73.08)	20 (68.97)	19 (65.52)
Researcher evaluation (n, 8%)	.6 (60.00).	12 (70.59)	18 (69.23)	18 (62.07)	22 (75.86)
Evaluation by a third-party professional doctor (n,%)	4 (40.00)	5 (29.41)	14 (53.85)	15 (51.72)	13 (44.83)
W2411 (n)	10	16	26	27	26
Subject self-assessment (n, 5%)	7 (70.00)	9 (56.25)	18 (69.23)	23 (85.19)	21 (80.77)
Researcher evaluation (n, 2%)	7 (70.00)	10 (62.50)	17 (65.38)	20 (74.07)	22 (84.62)
Evaluation by a third-party professional doctor (n,%)	4 (40.00)	6 (37.50)	15 (57.69)	17 (62.96)	15 (57.69)

•Remarks: "Support the n-27 evaluated by HGA third-party professional doctors for 2.5 mg BID after the line 6 network; the efficiency is calculated according to the evaluation results of the Line 7 classification method, and the scoring results are 1, 2, and 3 points. Subject is the law . W6DI means that the evaluation time is the first day of the A high, W12D1 indicates that the evaluation time is the first day of the 12th high, and W18D1 indicates that the evaluation time is the 18th plus the first day. W24D1 means that the evaluation time is the first day of week 24.

◆ Security analysis

• After 14 days of topical use, the systemic exposure of KX-826 and its metabolite KX-982 in vivo reached steady state; percutaneous blood entry in each dose group The concentration of the drug is low, the detectable blood concentration of KX-826 is 0.3-4.1 ng/mL, and the blood concentration of KX-982 is 0.4-10.4 ng/mL. • There were 3 cases of dose reduction due to adverse events (AE). According to the common adverse event evaluation standard 5.0, they were Grade 1 contact dermatitis and Grade 2 contact dermatitis. Grade Piyan and Grade I Ziku Disease.

• The incidence of adverse drug reactions (ADR) was 16.1%. The most common ADR was Shengku disease (5.9%), followed by contact dermatitis. (2.5%); 1 case had grade 3 hyperglyceridemia and grade 4 hyperglyceridemia once each, but the baseline triglyceride value was higher. (6.99mmol/L).

• No serious adverse events, no serious ADR and no deaths occurred.

conclusion ;

• Chinese adult male AGA patients (Hamilton-Norwood graded as Grade Illv, IV, and V) are treated with KX-826 5 mg BID topically and externally. After 24 weeks of treatment, there was a significant increase in TAHC in the target area compared to the safe agent. The overall safety of KX-826 in each dose group was good, and no pre-treatment was found. Unexpected new security incidents.In the 24th week of the 5 mg (0.5% concentration) BID group, TAHC increased by 15.34 roots/cm2 compared to the safe state and group., There is a statistical difference (p = 0.024). • KX-826 5 mg BID is recommended as the dose for a confirmatory phase I clinical trial.

If you have any questions or suggestions, please feel free to contact us 联系方式:rmzjz@126.com .