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DAEWOONG PHARMACEUTICAL CO.,LTD.

Baseline Clinical and Functional Spectrum of Idiopathic Pulmonary Fibrosis Patients in a Fully Enrolled Global Phase 2 Trial of the PRS Inhibitor Bersiporocin

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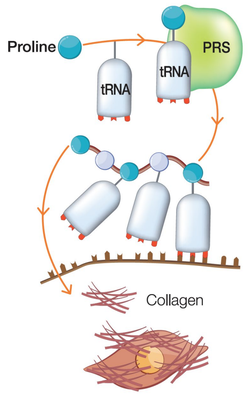
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BACKGROUND

- Idiopathic pulmonary fibrosis (IPF) is a progressive fibrosing interstitial lung disease characterised by heterogeneous clinical trajectories.
- Patients entering clinical trials may differ substantially in disease severity, functional impairment, and use of background antifibrotic therapy.
- Bersiporocin (DWN12088) is an oral prolyl-tRNA synthetase inhibitor being investigated for the treatment of IPF.
- Characterising the baseline profile of a fully enrolled global Phase 2 population is important for interpreting subsequent efficacy and safety outcomes.

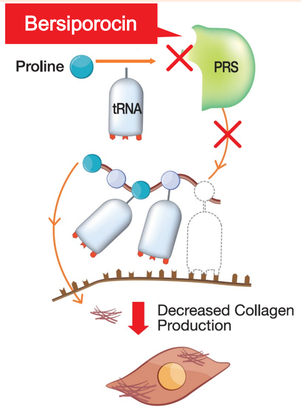
MECHANISM OF ACTION

Collagen biosynthesis - related Fibrosis



Progression of Fibrosis

PRS inhibition as Mechanism for collagen biosynthesis



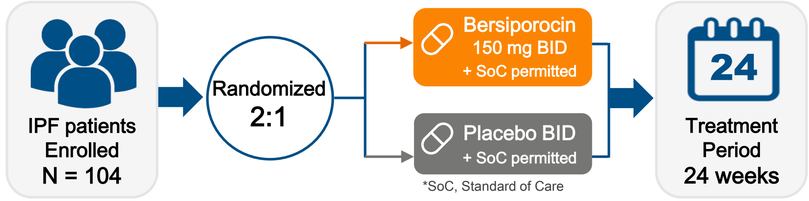
Inhibition of Fibrosis

▶ Bersiporocin inhibits prolyl-tRNA synthetase (PRS), an enzyme that attaches proline to its tRNA. By blocking this step, it reduces excessive collagen production and attenuates fibrosis. This mechanism supports Bersiporocin as a promising candidate for IPF treatment.

Proline: a key amino acid in collagen; tRNA: transfer RNA.

METHODS

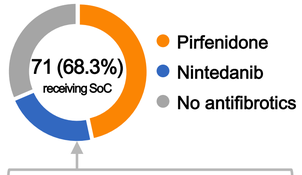
- This randomized, double-blind, placebo-controlled Phase 2 trial (NCT05389215) enrolled 104 patients with IPF across South Korea and the United States.
- Patients were randomized 2:1 to receive bersiporocin 150 mg twice daily or placebo for 24 weeks.
- Randomization was stratified according to background antifibrotic therapy use: pirfenidone or nintedanib versus no background antifibrotic therapy.
- Baseline demographic, disease, and functional characteristics were summarized overall and according to background antifibrotic therapy use.



RESULTS

Baseline Population Overview (N=104)

Background antifibrotic therapy at baseline



N = 48 (47.1%) | N = 23 (22.1%) | N = 33 (31.7%)

*One subject received both pirfenidone and nintedanib.

Lung function (overall)



FVC 77.5% predicted | DLCO 51.4% predicted

Geographic distribution



South Korea 55 (52.9%)

United States 49 (47.1%)

- A total of 104 patients were enrolled, including 71 (68.3%) receiving background antifibrotic therapy.
- Baseline characteristics were generally comparable between treatment groups, although patients without background antifibrotic therapy had numerically higher baseline FVC.

TABLE. Baseline Characteristics (N=104)

Characteristic	Overall	Background antifibrotic* use	No background antifibrotic use
Number of patients, N	104	71	33
Age, years	71.6 ± 6.6	71.0 ± 6.3	73.3 ± 6.9
Female, n (%)	10 (10.6)	8 (11.3)	2 (9.1)
Male, n (%)	94 (89.4)	63 (88.7)	31 (90.9)
Race, n (%)			
White	43 (41.3)	31 (43.7)	12 (36.3)
Black or African American	1 (1.0)	1 (1.4)	-
Asian	57 (54.8)	37 (52.1)	20 (60.6)
Other	3 (2.9)	2 (2.8)	1 (3.0)
Body Mass Index (kg/m^2)	26.0 ± 3.2	26.0 ± 3.3	26.2 ± 3.1
FVC% predicted	77.3 ± 16.5	76.5 ± 15.7	79.2 ± 17.8
DLco% predicted	51.3 ± 13.5	51.5 ± 14.1	49.8 ± 12.7

*Background antifibrotic therapy includes nintedanib and pirfenidone.
All continuous variables are presented as mean ± SD.

CONCLUSION

- This fully enrolled global Phase 2 study enrolled a clinically and functionally heterogeneous population of patients with IPF.
- Baseline characteristics were generally comparable regardless of background antifibrotic therapy use.
- These findings provide an important foundation for interpreting subsequent efficacy and safety results.

Scan to view the e-Poster