

SSH-005 (Congenital hypotrichosis treatment drug): Summary

SSH-005 could be a new treatment option for congenital hypotrichosis.

Hypotrichosis is a congenital disease that refers to a condition in which there is little or no hair growth from birth, and it is estimated that there are approximately 10,000 patients in Japan. It is caused by a mutation in the IPH gene, and is inherited in an autosomal recessive manner. There is no established treatment that can fundamentally cure hypotrichosis.

NcPA (Natural cyclic lysophosphatidic acid) has already been used in cosmetics and its hair growth effects have been confirmed. 2ccPA which is a synthetic derivative of NcPA and API of SSH-005 has potential for use in congenital hypotrichosis. SANSHO is developing SSH-005 for hypotrichosis as an orphan drug and obtained a patent for the hair growth effects of 2ccPA.

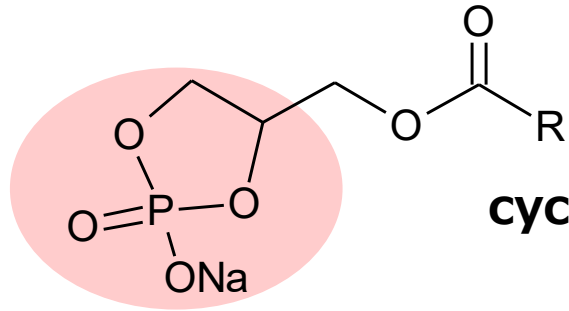
SANSHO Development Pipeline

	Non-clinical to Pre-clinical	Phase I	Phase II
Orthopedics		SSO-001 (OA*)	
Respiratory Medicine	SSI-002 (IPF**)		
Ophthalmology	SSG-003 (Glaucoma)		
Dermatology	SSD-004 (Scleroderma) SSH-005 (Hypotrichosis)		

*Osteoarthritis

**Idiopathic pulmonary fibrosis

Conversion of cPA to chemically stable derivatives



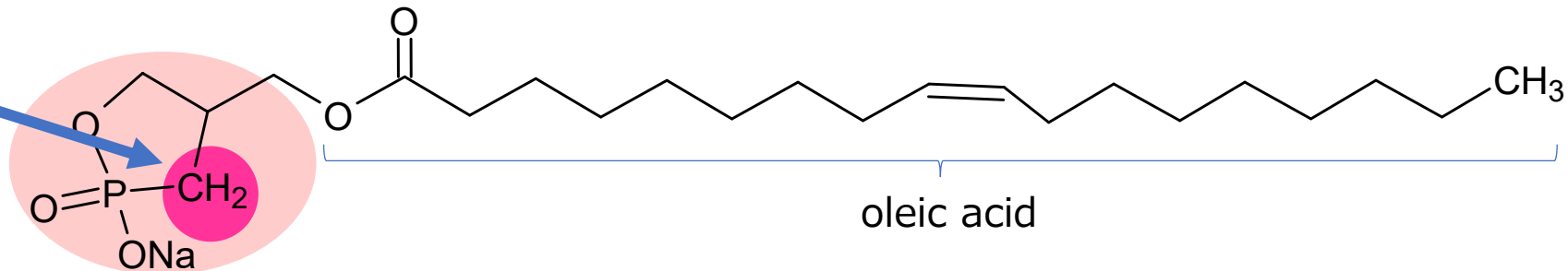
Various fatty acids such as linoleic acid, palmitic acid, and oleic acid

cyclic Phosphatidic Acid (cPA, R=C:16~22)

Improved in vivo stability by converting oxygen (O) to methylene (CH₂)



Conversion to chemically stable derivative



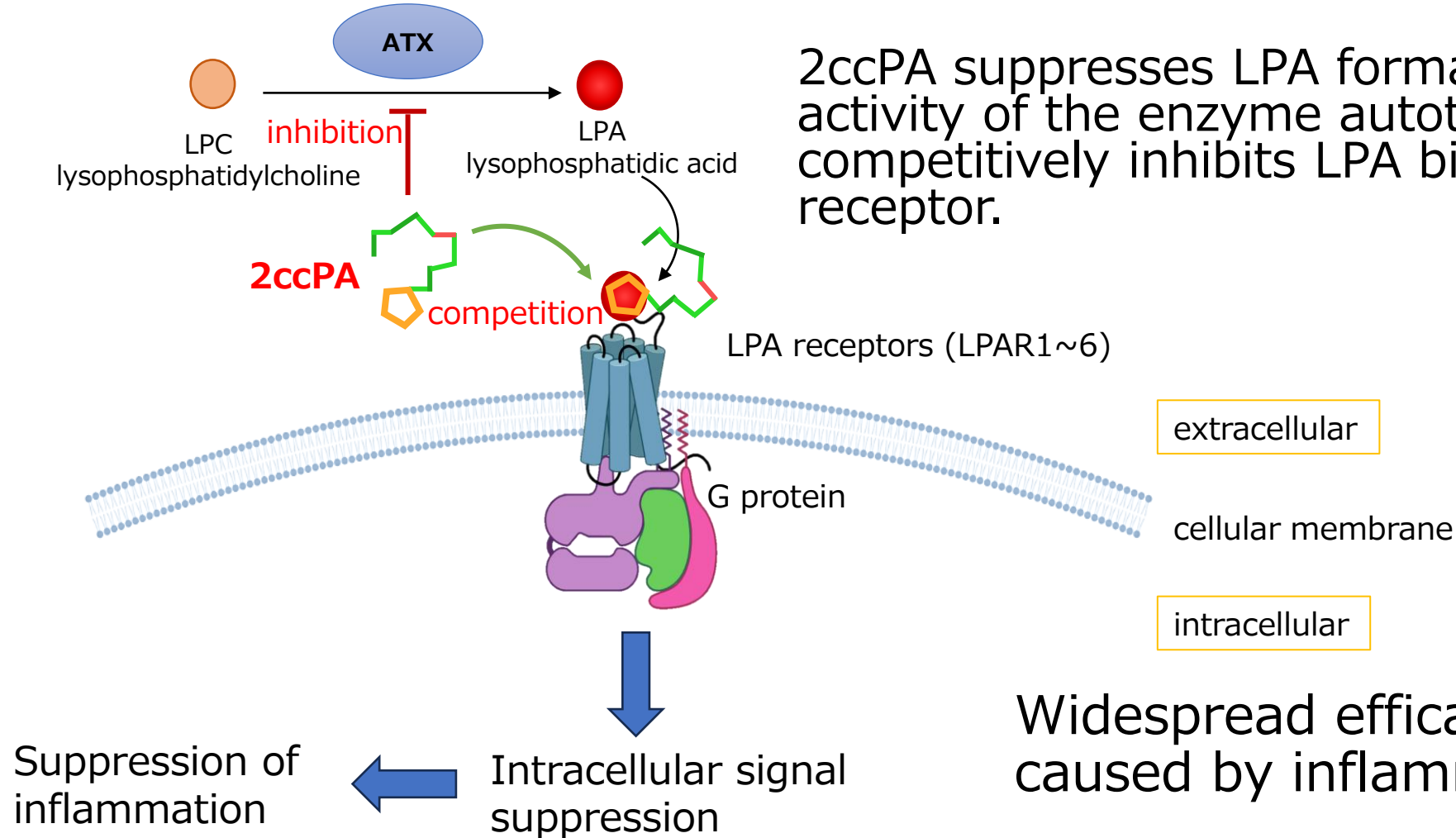
oleic acid

2-carba-cyclic phosphatidic acid (2ccPA)

Oleic acid is selected as the fatty acid

Unique mechanism of action of 2ccPA

2ccPA suppresses LPA formation by inhibiting the activity of the enzyme autotaxin (ATX) and competitively inhibits LPA binding to the LPA receptor.



Widespread efficacy in diseases caused by inflammation

Development of SSH-005 (a drug for the treatment of congenital hypotrichosis)

What is congenital hypotrichosis?

- A congenital disease that refers to a condition in which there is little or no hair growth from birth, and it is estimated that there are approximately 10,000 patients in Japan.
- It is caused by a mutation in the IPH gene, and is inherited in an autosomal recessive manner.
- There is no established treatment that can fundamentally cure hypotrichosis, but topical medications such as minoxidil are used to alleviate the symptoms.

Development Plan

- As both the natural cosmetic ingredient NcPA® and the synthetic derivative 2ccPA have potential for use in congenital hypotrichosis, we plan to seek early availability of NcPA® and to begin pharmaceutical development of 2ccPA as an orphan drug.

Development of SSH-005 (a drug for the treatment of congenital hypotrichosis)

Hair growth effect of NcPA in humans

Male, age 68

0.5% NcPA solution/30% 1-3BG, 1ml after bathing, apply once a day

From three months to six months, apply approximately 1 ml twice a day, after bathing and in the morning.



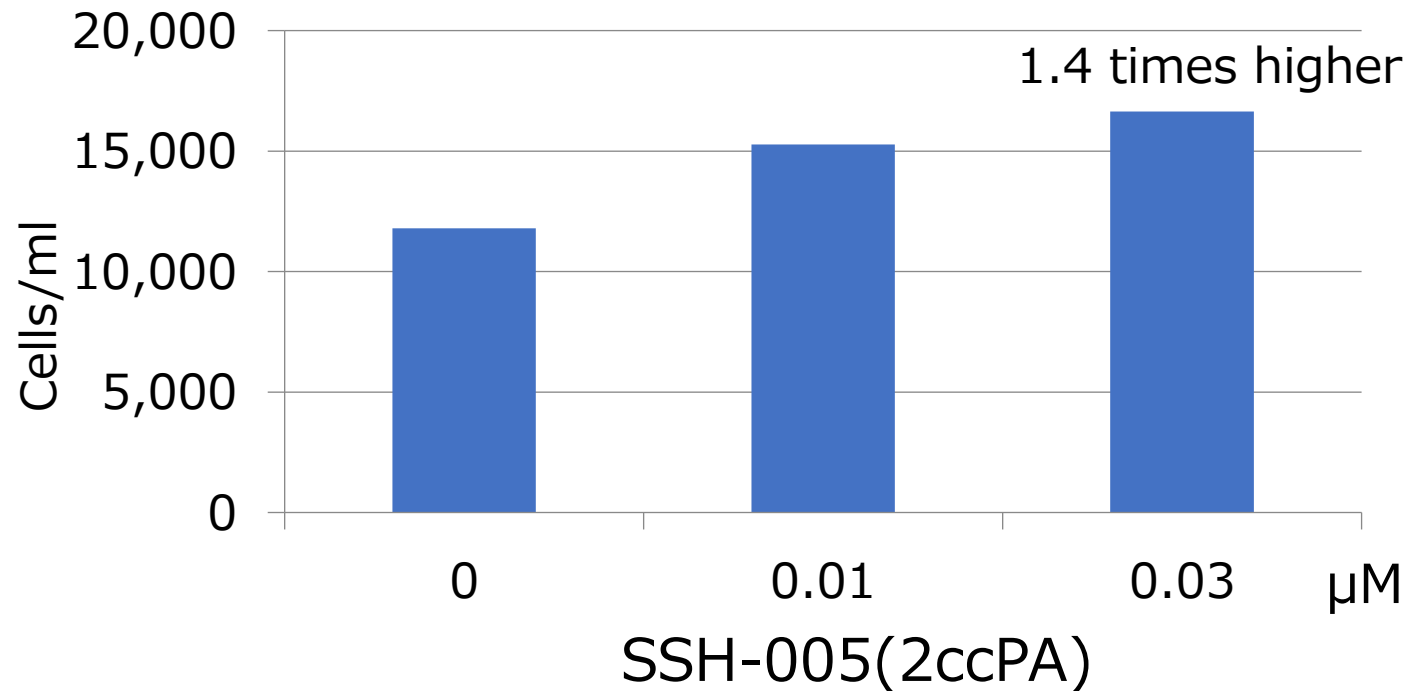
Hair regrowth effect confirmed in humans

Development of SSH-005 (a drug for the treatment of congenital hypotrichosis)

Promoting the growth of human hair papilla cells

[Method]

Human hair papilla cells were treated with SSH-005(2ccPA) and the number of cells was measured after 48 hours of incubation.



SSH-005(2ccPA) has a proliferative effect on human hair papilla cells.