



Supplementary materials for Aug 13, 2020 announcement

Agreement regarding exclusive in-license of new pipeline SP-05 and Financing

August 13, 2020
Solasia Pharma K.K. (Ticker:4597)

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1. Summary

Agreement regarding SP-05 exclusive in-license

- ✓ Exclusive development and commercialization rights for SP-05 (arfolitixorin) in Japan

Use of proceeds for this Financing

- ✓ R&D investment, etc for SP-05, SP-04, SP-02

Issuance of unsecured straight bond and warrants

- ✓ Utilize proceeds from the bond to timely commencement Phase III clinical trials for new pipeline SP-05 which was in-licensed today

2. Product/R&D pipeline – Product development progress & future investment

Pipeline Code Estimated Initial indication	Originator	Pre-clinical	Clinical Study			NDA	Approval	Launch	Out-licensed Partner (Region)
			Phase I	Phase II	Phase III				
SP-01 Sancuso® Chemotherapy Induced Nausea and Vomiting	Kyowa Kirin (UK)	China (Launched, Mar. 2019)						- Kyowa Kirin (TW etc.), - Lee's Pharma (China*) *excl. BJ, SH and GZ - Solasia sales force (above 3 big cities in China) Distribution partner; Itochu Corp.	
		Taiwan, HK etc. (by Kyowa Kirin)							
SP-02 darinaparsin Peripheral T-Cell Lymphoma	ZIOPHARM Oncology (US)	Japan, Korea, TW, HK				(Pivotal PII study completion, preparation for NDA filing)		- Meiji Seika Pharma (Japan), - HB Human BioScience (Latin America)	
		China		(Phase II/III, pivotal study preparation)					
		US		(Phase IIA, completion)					
		EU		(Pre-clinical, completion)					
SP-03 episil® [Medical Device] Pain associated oral mucositis	Camurus (Sweden)	Japan (Launched, May 2018)						- Meiji Seika Pharma (Japan), - Lee's Pharma (China*) *excl. BJ, SH and GZ - Solasia sales force (above 3 big cities in China) - Synex (South Korea) Distribution partner; Itochu Corp.	
		China (Launched, Jul. 2019)							
		Korea (Approved, Oct. 2019)							
SP-04 PledOx® Chemotherapy Induced Peripheral Neuropathy	PledPharma (Sweden)	Japan, Korea, TW, HK				(Phase III, pivotal study) Plan: early data cut-off in 3Q/2020, including EU and US		- Maruho (Japan)	
		China		(Clinical study preparation)					
SP-05 arfolitixorin Increase efficacy of fluorouracil	Isofol Medical (Sweden)	Japan				(Phase III, pivotal study)			
[Joint R&D 1] Nucleic acid drug candidate for peritoneal metastases (disseminated metastases developing in the peritoneum) : Option agreement for in-license of worldwide rights with GeneCare Research Institute Co., Ltd.									
[Joint R&D 2] New drug candidates for rare disease and/or oncology based on RNA editing technology utilizing pentatricopeptide repeat (PPR) protein platform technology : Joint R&D agreement with EditForce Inc.									

③ Development of indication line extension, Development investment in China

② Development investment in case additional clinical development is required

① Immediately invest in Global Phase III clinical study

④ Plan the in-licensing looking the development progress. Raise reserve funds for development investment

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3. SP-05 in-license agreement, Description of SP-05

Agreement for in-license of new pipeline SP-05

- ✓ Exclusive development and commercialization rights for SP-05(arfolitixorin) in Japan
- ✓ Global Phase III clinical study is on going, and Solasia will continue development in Japan
- ✓ Plan disclosure the result of interim analysis in 2021

【Agreement for exclusive in-license in Japan】

- Agreement with public biotech company Isofol Medical AB (“Isofol”) for exclusive in-license of new pipeline (Development code: SP-05, Generic name: arfolitixorin) in Japan
- Upon this agreement, Solasia has acquired **exclusive rights for development commercialization of SP-05 in Japan**

【What is SP-05 (arfolitixorin)?】

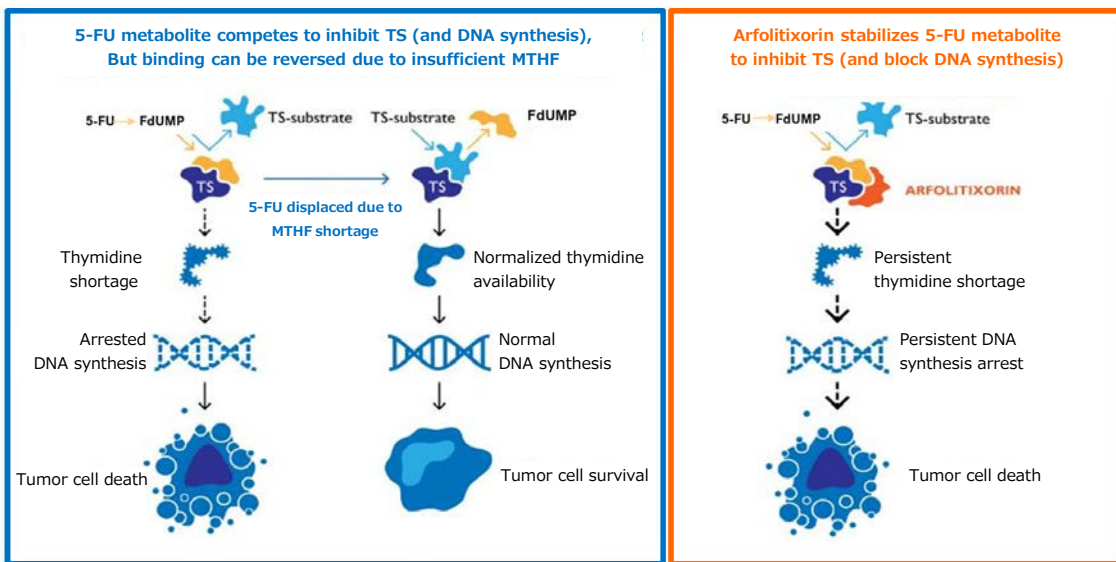
- Expected to **to increase in the antitumor efficacy of fluorouracil** which is an existing anticancer drug used as standard therapy for various cancer treatments, especially colorectal cancer, etc
- Currently, in areas such as North America, Europe, Oseania, and Japan, Isofol already conducts **Global Phase III clinical trial, and with the agreement, Solasia will takeover the development commercialization in Japan**

【Economic terms of in-license agreement】

- Solasia will pay Isofol a total amount of up to JPY 10.4 billion (approximately USD 100 million) as upfront, development, regulatory and sales-based milestone payments and clinical development cost. In addition, Solasia will pay royalties on net sales

3. SP-05 (arfolitixorin)

【Mechanism of Action of SP-05(arfolitixorin)】



【Clinical Trial Overview】

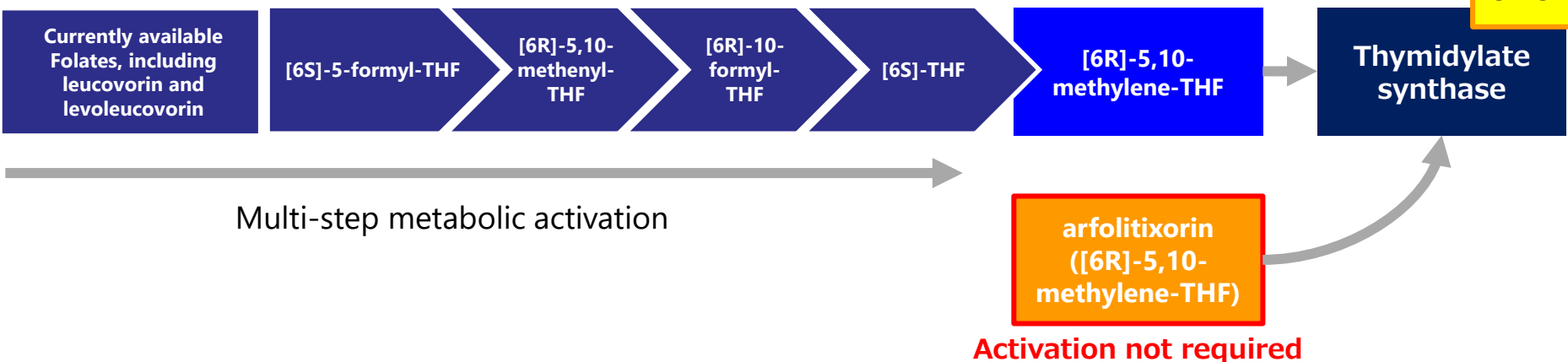
Study Design : A randomized, multicenter, parallel-group, Phase III study to compare the efficacy of arfolitixorin versus leucovorin in combination with 5-FU, oxaliplatin, and bevacizumab in patients with advanced colorectal cancer

Primary Endpoint : Overall Response Rate (ORR)
(Ratio of complete response plus partial response for tumor shrinkage)

Study Countries : USA, Canada, Europe, Australia, Japan

Target # of cases : 440~660
(Interim analysis planned on 330 cases :
Scheduled to announce interim analysis results within 2021)

【Multi-step activation of folates】



5-FU, 5-fluorouracil; THF, tetrahydrofolate.

4. Financing ～① Use of proceeds

Issuance of unsecured straight bond and warrants

- ✓ Utilize bond proceeds timely commencement of Phase III clinical trials for new pipeline SP-05 which was in-licensed today

【In-license and development cost for SP-05】 JPY2.0bn

- Together with JPY1.689bn received as proceeds from issuing new shares to Maruho Co., Ltd. last December, expect to utilize for One time in-license payment, milestone payment, development cost, etc, as well as development investment until commercialization in Japan

【Development for SP-04】 JPY2.0bn

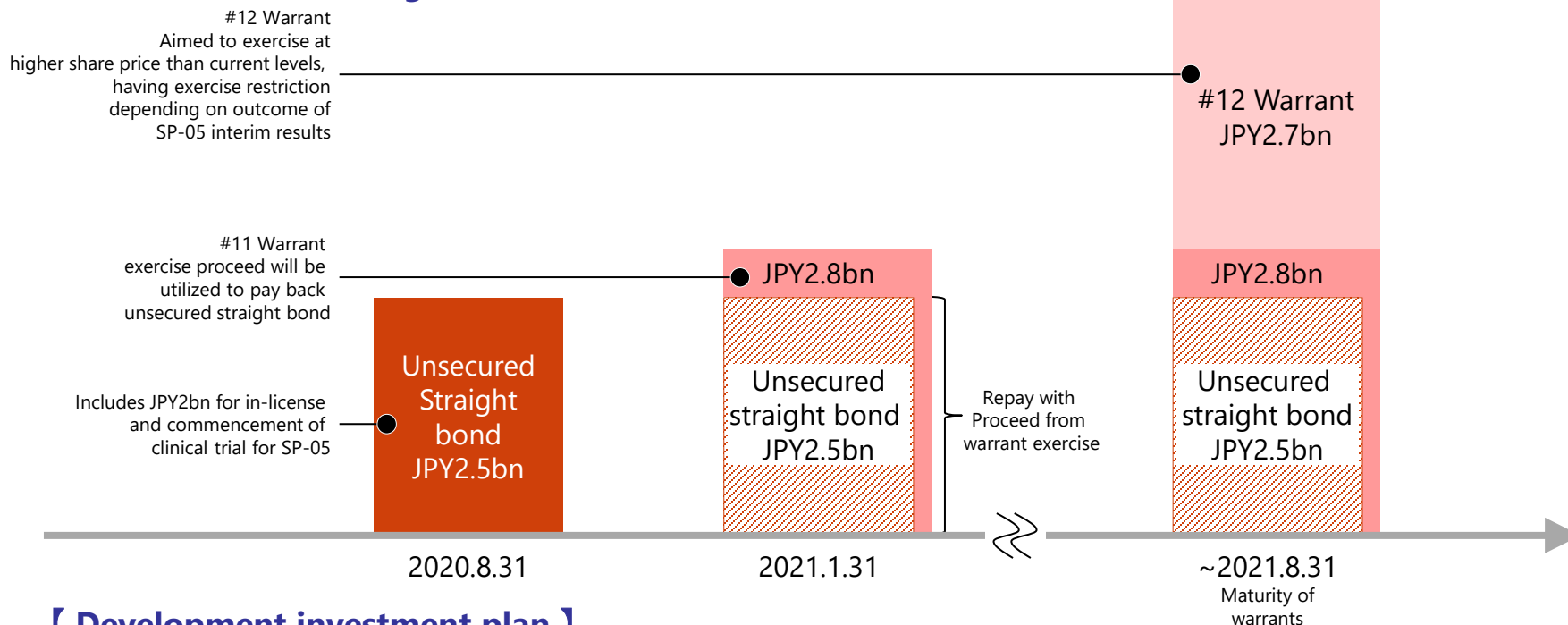
- Utilize for potential additional clinical development going forward
- In regards to additional clinical development, data cut off by Q3 2020, and decide on development plan and commence additional trials by Q1 2021

【Development for SP-02】 JPY1.5bn

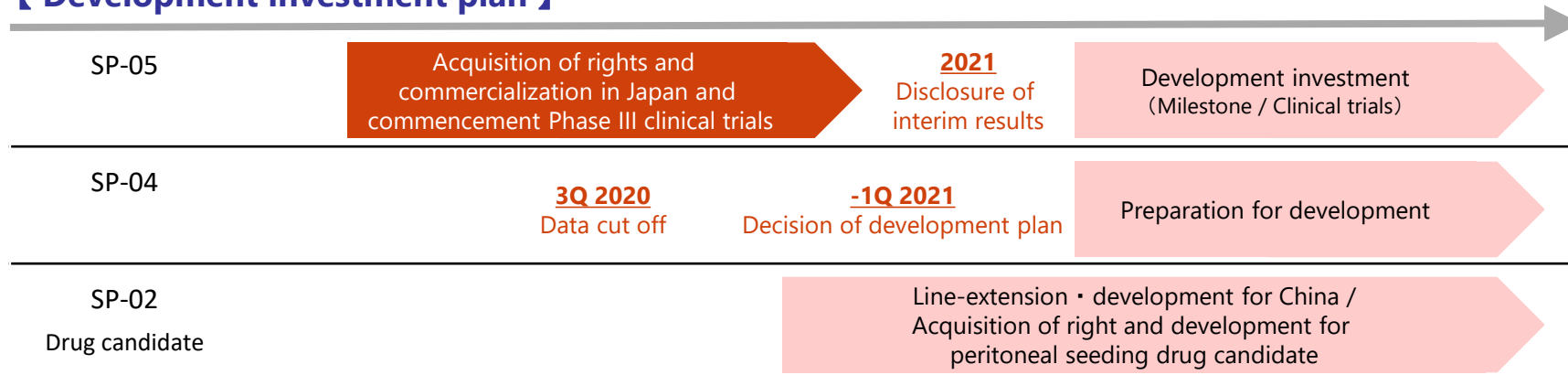
- SP-02, which has cleared key evaluation outcomes in the final clinical trial for Peripheral T-cell lymphoma, Solasia will utilize proceed to aim to line-extension development and development for China
- Assessing the progress of peritoneal seeding drug candidate which Solasia acquired exclusive negotiations rights in July 2020, Solasia will look to acquire the right and develop, and utilize the proceeds for development

4. Financing ~② Development investment plans

【 Structure of Financing 】



【 Development investment plan 】



4. Financing ~③ Financing method

Issuance of unsecured straight bond and warrants

- ✓ Accomplish one-time financing and timely capital raise by combining unsecured straight bond and warrants

Method	JPY	Summary	Feature and reason for the financing structure
Unsecured straight bond	2.5bn	<ul style="list-style-type: none"> ➤ Coupon 0.0% ➤ Term 1 year (Maturity Aug 31, 2021) 	<ul style="list-style-type: none"> ➤ To accomplish immediate investment for SP-05 and SP-04, <u>selected unsecured straight bond which raises cash upfront at issuance date at once</u> ➤ Expect <u>repayment of the bond by exercise of the warrant</u> which is issued concurrently
#11 Warrant	2.8bn	<ul style="list-style-type: none"> ➤ MS warrant where strike price resets from issuance ➤ 14,000,000 shares (11.98 of S/O) ➤ Floor exercise price JPY121 (60% of Aug 12, 2020) ➤ Strike price resets to 92% of previous close of exercise day 	<ul style="list-style-type: none"> ➤ Proceed from the exercise will be utilized to pay back the bond ➤ Commitment by the allotted party to exercise all of #11 warrant within 100 qualified trading days from issue date for the redemption of a certain amount of the bond
#12 Warrant	2.7bn	<ul style="list-style-type: none"> ➤ Fixed strike price of JPY300 ➤ 9,000,000 shares (7.70% of S/O) ➤ May switch to MS warrant upon board approval (floor price post the switch equal to that of #11 warrant) ➤ Also, upon completion of # 11 warrant, if unsecured straight bond is outstanding, will switch to MS warrant and proceed will be utilized to pay back the bond 	<ul style="list-style-type: none"> ➤ <u>Set a fixed strike price</u> and aim to <u>finance at higher share price than current price</u> ➤ <u>Exercise conditions in regards to SP-05</u> Interim results for Phase III clinical trial for SP-05 is publicly disclosed and must be that <ol style="list-style-type: none"> ① Completed successfully and will move to preparations for the New Drug Application or ② Solasia can continue the clinical trials after the interim results because the results are positive <p>Exercise condition is invalid before bond redemption completion / exercise commitment period by the Allottee / post switch to MS warrant</p>

5. Relationship with major shareholders

➤ Itochu Corporation (Top shareholder)

- ✓ Investor of Solasia since establishment, and current top shareholder (19.55 of S/O as of June 30 2020)
- ✓ Distribution agreement for China : Have signed agreement regarding Solasia's products distribution in China
- ✓ Business consignment agreement : Agreement of business consignment contract regarding providing information centered on pharmaceutical industry and China, proposal and assistance on acquisition of new rights and in-licensing
- ✓ Agreement on continuous ownership : 1 year lock up since Dec 26, 2019

As above, Solasia has established capital ties, business relationship, and varieties relationships with Itochu, and will continue to have good and stable relationship with Itochu

➤ Maruho Co., Ltd. (#2 shareholder)

- ✓ Exclusive distribution rights for SP-04: Partner for SP-04 distribution in Japan
- ✓ Capital alliance : #2 shareholder (9.68% of S/O as of June 20, 2020)
- ✓ Agreement on continuous ownership : Agree on lock up until announcement of first results of clinical trial after the two currently on-going Phase III clinical trials

Disclaimer

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