Intrommune plans Phase I peanut allergy trial in 1Q, USD 10m Series B raise in the next few months, CEO says

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Intrommune Therapeutics is starting its 32-patient Phase I study to assess its oral mucosal immunotherapy INT301 to treat peanut allergies this quarter, said CEO Michael Nelson. The company also plans to kick off a USD 10m Series B fundraise in the next month or so to support a Phase II trial for the same indication which will start later in 2021, Nelson said.

New York-based Intrommune has an active IND for INT301 as per a 4 February press release. The Phase I study will be followed by the Phase II which will enroll around 200 participants. The Phase II protocol will extend to the maintenance dose and will end with a food challenge to assess the therapy's efficacy, Nelson said. While the Phase II design is almost done, the Phase I experience will guide the starting dose and time for which the updosing protocols may continue, he added. The experience with pharma allergy company Aimmune Therapeutics, recently acquired by **Nestle** (SIX:NESN), and **DBV Technologies** (NASDAQ:DBVT) in developing therapies for peanut allergies have helped streamline the plans for Phase II and Phase III development, he added.

This news service had reported on 17 August 2020 on logistical challenges in administering allergy treatments, including FDA-approved Aimmune's oral immunotherapy (OIT) Palforzia (peanut allergen powder), due to the pandemic. Peanut allergy treatments like Palforzia involve an initial dose escalation and updosing component where increasing amounts of the allergen are administered followed by a maintenance phase. The Phase I INT301 trial will explore a shorter updosing schedule of 2–4 months which if effective would be more convenient than the current standard of longer schedules, said Nelson.

INT301 is an oral mucosal immunotherapy (OMIT) that relies on a toothpaste delivery system to deliver allergenic proteins to immunologically active areas in the oral cavity. Unlike OIT, the first day of dosing INT301 will not involve multiple updosing protocols and patients will have to spend a limited time in the medical office, Nelson said. After being updosed, participants will brush their teeth at the clinic, be monitored for an hour, and then need to visit the clinic for the next updosing level, like with OIT, he added.

While the company is starting with a focus on peanut allergies, Nelson envisioned multiallergen products where different foods could be dosed in one "toothbrushing" and reduce the number of therapies used to treat food allergies. Ongoing research and discussions through 2021 will guide which food-based allergy is chosen next, he added.

For the Series B round, Intrommune is in talks with capital sources, including private equity and venture capital entities, said Nelson. Additionally, Intrommune is considering

a host of institutions and advisors to raise the money, but he did not elaborate further. Closing the round quickly will enable the YE21 start for the Phase II study, Nelson added.

The company is currently closing its Series A round that was initially intended to fund the IND but since it was oversubscribed, the resultant funds would be enough to complete the Phase I trial, he said. Additionally, the funds would also support preliminary work for the Phase II study and multiallergen product, said Nelson. He declined to comment on the amount raised in the Series A given that it has not closed yet, but said the initial target was USD 1.4m and eventual raise is "well above that." This news service had reported Intrommune raising USD 155K at a valuation of USD 15m prior to the IND filing, on 10 October 2019. Now following the oversubscribed Series A and the developmental advances in 2020, Nelson said Intrommune's current valuation is significantly higher.

Intrommune has engaged Buffalo, New York-based integrated research organization **Circuit Clinical** to manage the Phase I study, as per a 20 October release. Moreover, Intrommune is exploring different strategies to ensure enrollment of subjects with peanut allergies, at the single site in New Jersey, including advertisements, Nelson said. Moreover, since the trial will enroll patients on a cohort-level, many participants will not be required at once which will help with accrual, he added.

by Manasi Vaidya in New York

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Indication:	Peanut Allergy
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Trial Identifier	Trial Phase	Trial Status
GDCT0335397	Phase I	Ongoing, recruiting
GDCT0412875	Phase II	Planned

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