



Scinai signs an option agreement to acquire rare disease company Pincell and its novel antibody for treating Severe Dermatological Conditions

Scinai files an application for Euro 12 million grant to fund the next stage of development

- Pincell's monoclonal antibody, PC111, is in development for treating Pemphigus, Steven Johnson's Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)
- PC111 has already received an Orphan Drug Designation in Pemphigus by the European Medicine's Agency
- An application will be filed with the FDA for Orphan Drug and Breakthrough Designation in Pemphigus, as well as in SJS/TEN
- Scinai sees potential for accelerated approval given the severity of these diseases, PC111's innovative, non-immunosuppressive mode of action and the lack of effective alternative treatments

JERUSALEM, ISRAEL – March. 27, 2025 - <u>Scinai Immunotherapeutics Ltd</u>. (Nasdaq: SCNI), ("Scinai", or the "Company"), a biopharmaceutical company focused on developing inflammation and immunology (I&I) biological products and on providing CDMO services through its Scinai Bioservices business unit, today announced that it entered into a binding option agreement for the acquisition of the Italian biotech company Pincell srl (<u>www.pincell.it</u>).

In anticipation of the signing of the option agreement, the parties have prepared together a grant application, submitted today by the wholly owned Polish subsidiary of Scinai, seeking Euro 12 million of non-dilutive capital to fund the next stage of development of PC111. To facilitate the submission of the application, Pincell exclusively licensed PC111 to the subsidiary. The grant application is under the European Funds for a Modern Economy (FENG) program in Poland. Subject to prior clearance of certain Italian regulatory formalities, an award decision is expected by mid-July/beginning of August.

About PC111

PC111, a fully human, monoclonal antibody that binds to the human soluble Fas ligand and thus blocks its activation of apoptosis of skin cells (keratinocytes). This pathway has a major role in several skin blistering disorders, characterized by a very high unmet medical need with significant market sizes. Importantly, PC111 does not suppress the immune system, at variance with many other biologicals treating inflammatory conditions that can lead to significant, at times fatal side effects.





Pincell has successfully developed a proprietary FasL humanized mouse model, with which it studied the involvement of the Fas/FasL pathway in these diseases, and that can be successfully used in other dermatological and non-dermatological diseases, where this pathway may play a key role in disease development and progression.

Pincell has carried out a large number of in-vitro, ex-vivo and in-vivo experiments using PC111 without steroids in validated models of pemphigus, to prove that soluble FasL is a critical target in this disease. Most importantly, Pincell has demonstrated that PC111 can block blister formation without steroids in a transgenic humanized FasL mouse model of pemphigus, indicating that the antibody can work also in a humanized setting and thus suggesting that it may be a novel targeted therapy for this disease at the clinical level. As there is abundant and convincing data supporting the critical role of soluble FasL also in the pathogenesis of SJS/TEN, PC111 could inhibit the mechanisms underlying the progression of this disease, as shown by the in vivo model where it ameliorates ocular conjunctivitis and edema, two main early features of this disease in humans, as well as its progression towards more severe forms.

About Pemphigus, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis

Pemphigus, Stevens-Johnson Syndrome (SJS), and Toxic Epidermal Necrolysis (TEN) are severe dermatological conditions that significantly impact the skin and mucous membranes. Pemphigus is an autoimmune disorder characterized by painful blisters and sores, often requiring long-term immunosuppressive medications for disease management, which are associated with a 5-10% mortality. Stevens-Johnson Syndrome is a rare but serious reaction to medications or infections, with a mortality rate of around 5-10%. Toxic Epidermal Necrolysis, the most severe form of SJS, involves extensive skin peeling and blistering over more than 30% of the body surface, with mortality rates ranging from 30-40%. These conditions highlight a significant unmet medical need for more effective treatments and better management strategies to improve patient outcomes and reduce mortality rates.

Amir Reichman, CEO of Scinai stated: "We are truly excited to have the opportunity to acquire Pincell and develop, in collaboration with the Pincell team, PC111 to treat these devastating skin disorders. Prof. Carlo Pincelli, founder and chief medical officer of Pincell, is considered a global leader in the dermatology field and in research relating to Pemphigus, and SJS/TEN. Dr. Antonino (Tony) Amato, Chairman and CEO of Pincell, is a recognized and highly accomplished executive in the biopharmaceutical sector, with significant international experience in senior management, clinical development and regulatory matters. Their skills and experience are highly complementary to our own and together we expect to advance the development of PC111 expeditiously."





Mr. Reichman added: "In addition, the grant we have applied for is under an EU program well suited to our development plans based on advice of a consultant in Poland who has helped prepare and process a number of other successful applications. While the application only covers the next stage of development, under current regulations we will have the opportunity to apply for successive grants in similar amounts if we achieve the target development milestones outlined in the initial application. As a result, the vast majority of the funding required for the project could be provided in the form of nondilutive grants, limiting our obligation to provide only one –fifth (Euro 3 million) of the budgeted amounts from our capital or capital raised via our Polish special purpose subsidiary. Combined with the potential for accelerated approval given the severity and lack of effective alternative treatments, we find the opportunity particularly appealing and a very good fit with our own I&I focus." Dr. Antonino Amato, Chairman and CEO of Pincell, commented: "We are very pleased to join forces with Scinai, a company with a great expertise in R&D of inflammatory skin diseases, as well as in the development and manufacturing of biologics. Their scientific knowledge, international reach and access to capital represent the ideal match to our development plans and needs. I am sure that this partnership will prove effective in the advancement of PC111 in the fight against Pemphigus and SJS/TEN, as well as, potentially, against other underserved dermatological and non-dermatological diseases involving the FasL/Fas receptor pathway in their pathomechanisms".

Option Terms

The option agreement allows Scinai, in return to an upfront payment, to exercise, at its sole discretion (pending on Scinai meeting closing requirements and approval of the Golden Power regulatory clearance by the Italian government), a full sale and transfer of Pincell's shares to Scinai by the end of 2025. If such share sale and transfer is exercised, Pincell's current shareholders will be eligible for development milestone payments and royalties out of future net sales of PC111 in the low single digits. In addition, the management team of Pincell will join Scinai's wholly owned, newly created subsidiary in Poland and Pincell's founder, Prof. Carlo Pincelli, will join Scinai's Scientific Advisory Board.

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