BIONEER
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Investor Relations Brief

2024

9 September

※ 바이오니아는 투자 판단에 참고할 만한 정보를 제공할 뿐이며 투자에 대한 책임은 투자자에게 있음을 알려드립니다.

Business Division Progress Report

Molecular Diagnostics

The Molecular Diagnostics and Marketing Division participated in the world's largest diagnostic testing conference and exhibition, 'ADLM 2024' (Association for Diagnostics & Laboratory Medicine), held in Chicago, USA, from July 30 to August 1, where they showcased innovative diagnostic devices such as the ExiCycler™ V5 and IRON-qPCR™. These presentations garnered significant attention from many experts in the field of laboratory medicine and industry stakeholders. Additionally, they successfully conducted about 100 meetings with partner companies. Furthermore, through the presentation of two clinical posters on the ExiStation™ FA 96 and IRON-qPCR™, the company demonstrated that its diagnostic equipment could reliably detect multiple respiratory viruses simultaneously with high sensitivity and specificity in a short amount of time.

CosmeRNA

The B2B business is expected to gain more momentum due to the recently launched B2B-exclusive product, CosmeRNA Intensive. The first order from Atlas Medical in the United Arab Emirates began in August, and promotional activities in Kuwait are scheduled to start in September ahead of local market entry.

In addition, we are actively pursuing global partnerships in various countries worldwide. Multiple companies in each country are interested in entering into exclusive agreements with us. We are thoroughly reviewing the candidates' experience, distribution networks, marketing capabilities, sales plans, and financial status to select the best partners. Given the positive initial responses from many global partners, we anticipate that the results of our efforts will soon become visible.

AceBiome

AceBiome’s flagship products, BNRThin and BNRThin Pro, were renewed and relaunched on August 18 under the motto "World Class Ingredient, Premium Look." Notably, BNR17Thin has improved user convenience by reducing the capsule size by 11% while maintaining the same main ingredients.

Additionally, we have launched a new product, ‘AceBiome Multivitamin’, which combines 23 kinds of multivitamins and minerals. Vitamins, along with ginseng, are among the top categories in the domestic health functional food market, competing for the 2nd to 3rd positions. The company plans to focus on cross-selling to BNRThin & BNRThin Pro customers based on the strong product competitiveness, thereby increasing sales and simultaneously attracting new customers.

siRNAgen

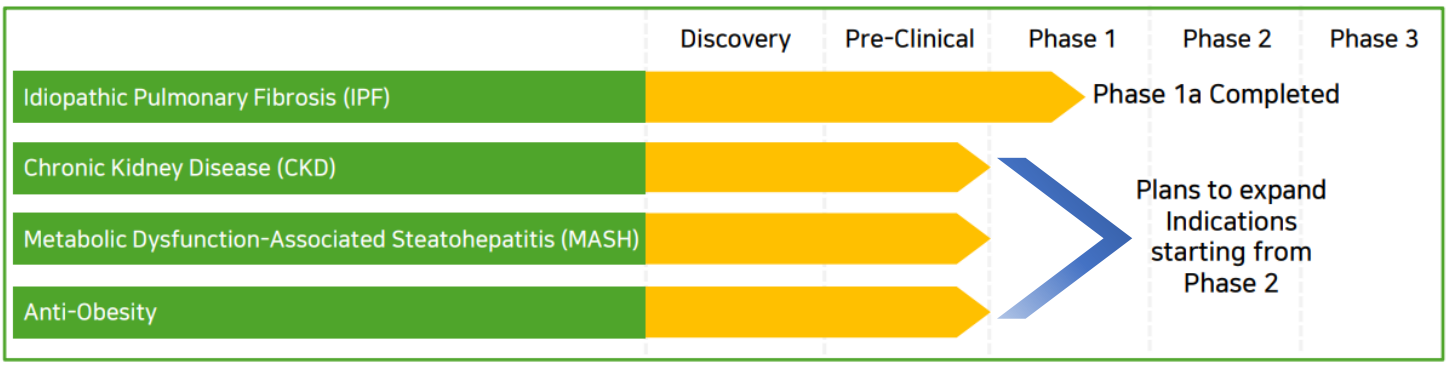
siRNAgen Therapeutics has completed the review of the results of the SRN-001 Phase 1a clinical trial and has begun drafting the final report. Specifically, the company has received a draft of the final report from the clinical CRO, reviewed it with internal and external experts, and provided initial feedback to the CRO. The final report is expected to be secured in September after two to three rounds of thorough review. The Clinical Study Report (CSR) is scheduled for September 25, but please note that this date may change depending on local circumstances.

Bioneer News

SRN-001 : Vision for the innovative New Drug

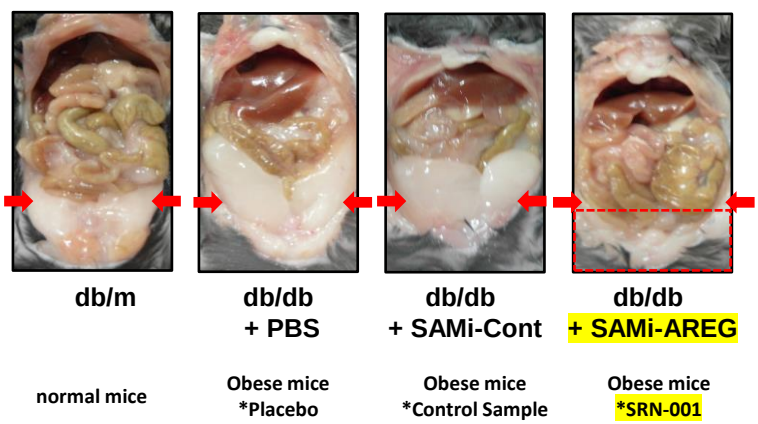
Bioneer confirmed high safety and tolerability in the draft report of the SRN-001 Phase 1a clinical trial. This trial marks **the first instance where siRNA, utilizing the SAMiRNA platform, was systemically administered to humans**. The study results indicated that even at a maximum dose approximately 10 times higher than the effective human-equivalent dose observed in disease mouse models, no significant adverse reactions were noted, thereby demonstrating a high level of tolerability. Additionally, pharmacokinetic (PK) results also confirmed a correlation between the administered dose and exposure levels.

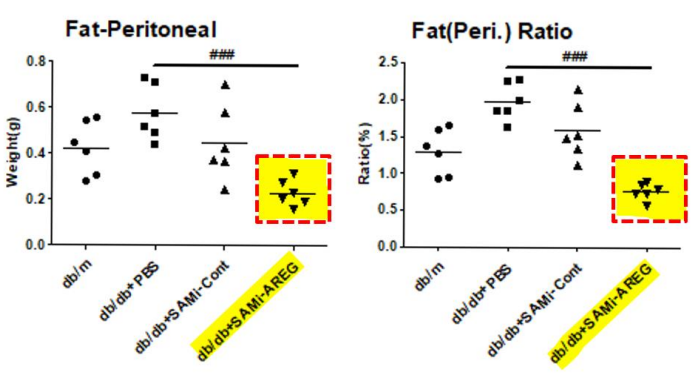
◉ SRN-001 Clinical Trial Status



After the successful completion of Phase 1 clinical trials, we are planning to **expand the indications for SRN-001 in Phase 2 to include chronic kidney disease (CKD), metabolic-associated steatohepatitis (MASH), and anti-obesity**. As recently disclosed in media reports, **Amphiregulin, the target of SRN-001, is known as a factor that not only promotes fibrosis expression but also stimulates fat generation**. In preclinical animal experiments on obese mice, SRN-001 demonstrated a reduction of about 70% in visceral fat percentage in white adipose tissue (WAT) compared to the control group. Additionally, it showed effectiveness in reducing body weight, subcutaneous fat, and adipocyte size, and in inhibiting the accumulation of fatty liver. These results suggest the potential application of SRN-001 in the treatment and prevention of complications from visceral fat, such as cardiovascular disease, metabolic disorders, diabetes, and other various conditions.

◉ SRN-001 Anti-obesity Preclinical Experiment Data





Bioneer News

SRN-001 : A New Paradigm in Obesity Treatment

- Distinctiveness from GLP-1 Based Treatments -

	GLP-1 Treatments	SRN-001 (Bioneer)
Mechanism of Action	GLP-1 analogs mimic the incretin effect to promote insulin secretion and delay gastric emptying, thereby increasing satiety and resulting in weight loss. However, this is an **indirect mechanism** for managing obesity.	SRN-001 targets a new adipogenic growth factor, Amphiregulin (AREG) mRNA, to inhibit its expression, thereby **directly suppressing both the proliferation and differentiation of adipocytes.** AREG mRNA is overexpressed in obese adipose tissue, and AREG-deficient mice are protected from insulin resistance. These results suggest that SRN-001 may have a direct impact on the physiological changes of adipocytes and the prevention of obesity-related diseases.
Dosage, Frequency, Safety	Typically, it needs to be administered **once a week or daily**, and long-term treatment may be required. This can cause some inconvenience to patients, and **side effects** such as nausea, vomiting, and constipation may occur.	siRNA-based therapies act at the mRNA level, making it possible to achieve therapeutic effects with **relatively low dosages and frequencies**. Since siRNA has specific and potent action, even a small amount can produce sufficient therapeutic effects, which can enhance **patient convenience**. Additionally, SRN-001, in a Phase 1a clinical trial conducted in Australia, showed no toxicity even at 10 times the effective dose, and as confirmed in non-clinical toxicity studies, its **superior safety** compared to FDA-approved siRNA therapies was also demonstrated in Phase 1a.
Half-life	The half-life is generally a few hours, and **continuous administration** is required to maintain the drug's effects.	siRNA can bind to the RISC complex within the cell and continuously degrade the target mRNA, allowing its effects to last longer. In fact, the siRNA-based hyperlipidemia treatment Leqvio (active ingredient: Inclisiran) is administered twice a year (once every 6 months), showing high patient compliance and significantly improving treatment convenience due **to its low dosing frequency.**

◉ Conclusion

SRN-001 may have potential advantages over GLP-1 based therapies in terms of mechanism of action, dosing frequency and dosage, half-life, and safety. This suggests the possibility of improving patient convenience and providing more sustained and fundamental therapeutic effects. However, the extent to which these advantages are effective in actual clinical settings needs to be confirmed through additional clinical research.

Bioneer News

ADLM 2024

ADLM is the world's largest diagnostic conference and exhibition where clinical specialists and industry professionals from around the globe gather to showcase the latest clinical laboratory products and services and present research findings. This year, over 780 companies participated, with Bioneer also presenting a variety of diagnostic products and continuing its marketing activities.