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NS-065/NCNP-01 (Viltolarsen) - Emerging Insight and Market Forecast - 2030

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Abstracts

This report can be delivered to the clients within 48 Hours

OVERVIEW

“NS-065/NCNP-01 (Viltolarsen) - Emerging Insight and Market Forecast – 2030” report by DelveInsight outlays comprehensive insights of the product indicated for the treatment of its approved condition. A detailed picture of the NS-065/NCNP-01 (Viltolarsen) in Seven Major Markets, i.e., United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan, for the study period 2017–2030 is provided in this report along with a detailed description of the product. The product details covers mechanism of action, dosage and administration, route of synthesis, and pharmacological studies, including product marketed details, regulatory milestones, and other development activities. Further, it also consists of market assessments inclusive of the market forecast, SWOT analysis, and detailed analyst views. It further highlights the market competitors, late-stage emerging therapies, and patent details in the global space.

Viltolarsen (NS-065/NCNP-01) is an experimental therapy that NS Pharma is developing, with its parent company Nippon Shinyaku, to treat Duchenne muscular dystrophy (DMD) resulting from mutations amenable to exon 53 skipping. It is an infusion that doctors administer into the bloodstream. NS Pharma announced in February 2020 that the U.S. Food and Drug Administration (FDA) accepted its request (called a new drug application or NDA) to review viltolarsen for possible approval. An FDA decision is anticipated in late summer or early autumn 2020. Viltolarsen contains an artificial piece of mRNA that masks exon 53, causing cells to “skip” this exon when they are making mature mRNA. This skip restores the so-called “reading frame” of the

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mRNA molecule. In other words, it ensures that the remaining exons fit together again, allowing a cell's protein-making machinery to synthesize a shorter but working dystrophin protein. Because viltolarsen is specific to exon 53, the treatment is effective only in those DMD patients who have a mutation that is amenable to exon 53 skipping. A Phase 3 study is actively recruiting. A Phase 2 study completed enrollment and dosing at clinical sites in North America (United States and Canada). All participants elected to enroll into an extension study. All participants continue to be dosed. On February 10, 2020, NS Pharma announced that the FDA has filed a New Drug Application (NDA) for their antisense oligonucleotide drug NS-065/NCNP-01 (viltolarsen). NS Pharma, Inc. shared an update with the community responding to questions about how COVID-19 may be affecting ongoing studies of viltolarsen, the recently launched Expanded Access Program (EAP) and review of the viltolarsen New Drug Application (NDA) by the FDA.

SCOPE OF THE REPORT

The report provides insights into:

A comprehensive product overview including the product description, mechanism of action, dosage and administration, route of synthesis, pharmacological studies (pharmacodynamics and pharmacokinetics) and adverse reactions.

Elaborated details on regulatory milestones and other development activities have been provided in this report.

The report also highlights the drug marketed details across the United States, Europe and Japan.

The report also covers the patents information with expiry timeline around NS-065/NCNP-01 (Viltolarsen).

The report contains historical and forecasted sales for NS-065/NCNP-01 (Viltolarsen) till 2030.

Comprehensive coverage of the late-stage emerging therapies (Phase III) in the space with a brief snapshot of the details.

The report also features the SWOT analysis with analyst insights and key

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findings of NS-065/NCNP-01 (Viltolarsen).

METHODOLOGY

The report is built using data and information sourced primarily from internal databases, primary and secondary research and in-house analysis by DelveInsight's team of industry experts. Information and data from the secondary sources have been obtained from various printable and nonprintable sources like search engines, news websites, global regulatory authorities websites, trade journals, white papers, magazines, books, trade associations, industry associations, industry portals and access to available databases.

NS-065/NCNP-01 (Viltolarsen) Analytical Perspective by DelveInsight

In-depth NS-065/NCNP-01 (Viltolarsen) Market Assessment

This report provides a detailed market assessment of NS-065/NCNP-01 (Viltolarsen) in Seven Major Markets, i.e., United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan. This segment of the report provides historical and forecasted sales data from 2017 to 2030.

NS-065/NCNP-01 (Viltolarsen) Clinical Assessment

The report provides the clinical trials information of NS-065/NCNP-01 (Viltolarsen) covering trial interventions, trial conditions, trial status, start and completion dates.

REPORT HIGHLIGHTS

In the coming years, the market scenario for NS-065/NCNP-01 (Viltolarsen) is set to change due to the extensive research in the treatment of the indicated condition and incremental healthcare spending across the world; which would expand the size of the market to enable the drug manufacturers to penetrate more into the market.

The companies and academics are working to assess challenges and seek opportunities that could influence NS-065/NCNP-01 (Viltolarsen) dominance.

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The therapies under development are focused on novel approaches to treat/improve the disease condition.

Other approved products for the disease are giving market competition to NS-065/NCNP-01 (Viltolarsen) and launch of late-stage emerging therapies in the near future will significantly impact the market.

A detailed description of regulatory milestones, development activities, and some key findings provide the current market scenario of NS-065/NCNP-01 (Viltolarsen).

Our in-depth analysis of the sales data of NS-065/NCNP-01 (Viltolarsen) from 2017 to 2030 will support the clients in the decision-making process regarding their therapeutic portfolio by identifying the overall scenario of the NS-065/NCNP-01 (Viltolarsen) in the market.

KEY QUESTIONS

What is the prescribed dosage and strengths of NS-065/NCNP-01 (Viltolarsen) are available in the market?

What are the common adverse reactions or side effects of NS-065/NCNP-01 (Viltolarsen)?

What is the product type, route of administration and mechanism of action of NS-065/NCNP-01 (Viltolarsen)?

What are the chemical specifications of NS-065/NCNP-01 (Viltolarsen)?

How are the clinical trials diversified on the basis of the trial status?

What is the history of NS-065/NCNP-01 (Viltolarsen), and what is its future?

What are the marketed details of NS-065/NCNP-01 (Viltolarsen) in the seven major countries, including the United States, Europe (Germany, France, Italy, Spain, and the United Kingdom), and Japan?

How many patents have been granted to NS-065/NCNP-01 (Viltolarsen) and

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when these patents will get expire?

What are the pros (benefits) and cons (disadvantages) of NS-065/NCNP-01 (Viltolarsen)?

In which countries NS-065/NCNP-01 (Viltolarsen) got approval and when it gets launched?

What are the clinical trials are currently ongoing for NS-065/NCNP-01 (Viltolarsen)?

How the safety and efficacy results determined the approval of NS-065/NCNP-01 (Viltolarsen)?

What are the key collaborations, mergers and acquisitions, licensing and other activities related to the NS-065/NCNP-01 (Viltolarsen) development?

What are the key designations that have been granted to NS-065/NCNP-01 (Viltolarsen)?

What is the historical and forecasted market scenario of NS-065/NCNP-01 (Viltolarsen)?

How is the market trend of NS-065/NCNP-01 (Viltolarsen) is different in the Seven Major Markets (the United States, EU5 [Germany, France, Italy, Spain, and the United Kingdom], and Japan)?

What are the other approved products available and how these are giving competition to NS-065/NCNP-01 (Viltolarsen)?

Which are the late-stage emerging therapies under development for the treatment of the indicated condition?

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