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Complicated Urinary Tract Infections - Pipeline Insight, 2021

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Abstracts

This report can be delivered to the clients within 48-72 hours

DelveInsight's, "Complicated Urinary Tract Infections – Pipeline Insight, 2021," report provides comprehensive insights about 12+ companies and 12+ pipeline drugs in Complicated Urinary Tract Infections pipeline landscape. It covers the pipeline drug profiles, including clinical and nonclinical stage products. It also covers the therapeutics assessment by product type, stage, route of administration, and molecule type. It further highlights the inactive pipeline products in this space.

Geography Covered

Global coverage

Complicated Urinary Tract Infections Understanding

Complicated Urinary Tract Infections: Overview

Urinary tract infections (UTI) are the most common bacterial infections involving lower (cystitis, prostatitis) or upper (pyelonephritis, renal abscess, perinephric abscess) urinary tract. Differentiation of complicated and uncomplicated UTI is usually based on the presence of structural or functional urinary tract abnormalities, which can increase the risk of treatment failure and development of serious complications. Factors that increase the risk are foreign bodies, stones, obstruction, neurogenic bladder, kidney transplantation, immunosuppression, and pregnancy. Complicated UTI includes a spectrum of conditions that increase the risk of treatment failure, as well as of serious

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complications such as bacteremia and sepsis, perinephric abscess, renal impairment and emphysematous pyelonephritis. A good quality urine specimen is vital in making the diagnosis. However, treatment must not be delayed if the clinical scenario is strongly suggestive of a urinary tract infection. Blood cultures are also useful in more severe septic presentations. A positive blood culture can sometimes also help corroborate a urine sample result and reduce the suspicion of contamination. Ultrasound and CT scans may sometimes be useful or even critical for diagnosing perinephric abscess, urinary retention, hydronephrosis and obstructive pyelonephritis from stones in septic patients. As UTI can present with severe, life-threatening sepsis and multiorgan involvement. Resuscitation often precedes definitive treatment. The severely septic patient might need aggressive fluid resuscitation as well as broad-spectrum antibiotics administered in the emergency department.

'Complicated Urinary Tract Infections - Pipeline Insight, 2021' report by DelveInsight outlays comprehensive insights of present scenario and growth prospects across the indication. A detailed picture of the Complicated Urinary Tract Infections pipeline landscape is provided which includes the disease overview and Complicated Urinary Tract Infections treatment guidelines. The assessment part of the report embraces, in depth Complicated Urinary Tract Infections commercial assessment and clinical assessment of the pipeline products under development. In the report, detailed description of the drug is given which includes mechanism of action of the drug, clinical studies, NDA approvals (if any), and product development activities comprising the technology, Complicated Urinary Tract Infections collaborations, licensing, mergers and acquisition, funding, designations and other product related details.

Report Highlights

> The companies and academics are working to assess challenges and seek opportunities that could influence Complicated Urinary Tract Infections R&D. The therapies under development are focused on novel approaches to treat/improve Complicated Urinary Tract Infections.

Complicated Urinary Tract Infections Emerging Drugs Chapters

This segment of the Complicated Urinary Tract Infections report encloses its detailed analysis of various drugs in different stages of clinical development, including phase II, I, preclinical and Discovery. It also helps to understand clinical trial details, expressive pharmacological action, agreements and collaborations, and the latest news and press

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releases.

Complicated Urinary Tract Infections Emerging Drugs

Tebipenem Pivoxil Hydrobromide: Spero Therapeutics

Spero Therapeutics is developing tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994) as an oral antibiotic for the treatment of complicated urinary tract infection (cUTI) and acute pyelonephritis (AP) to help patients avoid hospitalizations (stay at home) and/or transition patients home after IV therapy (get home). In September 2020, tebipenem HBr completed a pivotal Phase III trial, ADAPT-PO, for the treatment of cUTI, including acute pyelonephritis (AP). ADAPT-PO is a landmark trial that is the first ever to test an all oral regimen against an all intravenous (IV) regimen for the treatment of cUTI. The global, randomized, placebo-controlled ADAPT-PO trial evaluated the safety and efficacy of tebipenem HBr in hospitalized adult patients with cUTI or AP. Data from the trial demonstrated that oral tebipenem HBr was statistically non-inferior to IV ertapenem in the treatment of patients with cUTI and patients with AP. If approved, tebipenem HBr would be the first oral carbapenem antimicrobial to receive marketing approval in the United States. Tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of cUTI and AP.

Sulopenem: Iterum Therapeutics

Sulopenem is an orally bioavailable, broad-spectrum penem ?-lactam antibiotic which is being developed for the treatment of infections caused by multi-drug resistant bacteria. Sulopenem was discovered in the laboratories of Pfizer Inc. in the 1980s and was first developed with an intravenous (IV) formulation only. The company completed an extensive pre-clinical program, followed by human studies. Later, an oral formulation was developed and tested in Phase I and Phase II trials. In November 2015, Iterum successfully negotiated the license of sulopenem and its prodrugs and restarted the development program. Iterum Therapeutics received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) on July 23, 2021. The CRL provided that the FDA has completed its review of the NDA and has determined that it cannot approve the NDA in its present form. The FDA determined that additional data are necessary to support approval for the treatment of adult women with

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uncomplicated urinary tract infections caused by designated susceptible microorganisms proven or strongly suspected to be non-susceptible to a quinolone.

Further product details are provided in the report.

Complicated Urinary Tract Infections: Therapeutic Assessment

This segment of the report provides insights about the different Complicated Urinary Tract Infections drugs segregated based on following parameters that define the scope of the report, such as:

Major Players in Complicated Urinary Tract Infections

There are approx. 12+ key companies which are developing the therapies for Complicated Urinary Tract Infections. The companies which have their Complicated Urinary Tract Infections drug candidates in the most advanced stage, i.e. Phase III include, Spero Therapeutics.

Phases

DelveInsight's report covers around 12+ products under different phases of clinical development like

Late stage products (Phase III)

Mid-stage products (Phase II)

Early-stage product (Phase I) along with the details of

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

Complicated Urinary Tract Infections pipeline report provides the therapeutic

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assessment of the pipeline drugs by the Route of Administration. Products have been categorized under various ROAs such as

Oral

Parenteral

Intravenous

Subcutaneous

Topical

Molecule Type

Products have been categorized under various Molecule types such as

Monoclonal Antibody

Peptides

Polymer

Small molecule

Gene therapy

Product Type

Drugs have been categorized under various product types like Mono, Combination and Mono/Combination.

Complicated Urinary Tract Infections: Pipeline Development Activities

The report provides insights into different therapeutic candidates in phase II, I, preclinical and discovery stage. It also analyses Complicated Urinary Tract Infections therapeutic drugs key players involved in developing key drugs.

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Pipeline Development Activities

The report covers the detailed information of collaborations, acquisition and merger, licensing along with a thorough therapeutic assessment of emerging Complicated Urinary Tract Infections drugs.

Complicated Urinary Tract Infections Report Insights

- Complicated Urinary Tract Infections Pipeline Analysis
- Therapeutic Assessment
- Unmet Needs
- Impact of Drugs

Complicated Urinary Tract Infections Report Assessment

- Pipeline Product Profiles
- Therapeutic Assessment
- Pipeline Assessment
- Inactive drugs assessment
- Unmet Needs

Key Questions

Current Treatment Scenario and Emerging Therapies:

- How many companies are developing Complicated Urinary Tract Infections drugs?
- How many Complicated Urinary Tract Infections drugs are developed by each

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company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Complicated Urinary Tract Infections?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Complicated Urinary Tract Infections therapeutics?

What are the recent trends, drug types and novel technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for Complicated Urinary Tract Infections and their status?

What are the key designations that have been granted to the emerging drugs?

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