

Cutaneous T-Cell Lymphoma Market Witnessing Growth at ~3% in the US by 2032, Examines Delvelnsight

How are companies such as Pfizer, Eisai, Citius, Bristol Myers Squibb, Merck, Kyowa Kirin, Seagen, and others influencing the CTCL market?

LAS VEGAS, CALIFORNIA, UNITED STATES OF AMERICA, March 21, 2024 /EINPresswire.com/ -- The total market size of CTCL in the 7MM was USD 500 million in 2022 and is projected to grow during the forecast period (2023–2032) due to an increase in the incident population of CTCL along with the expected launch of emerging therapies such as I/ONTAK (Citius Pharmaceuticals), HyBryte (Soligenix), Resminostat (4SC AG), Lacutamab (Innate Pharma), exoIL-12 (Codiak), and others.

DelveInsight's Cutaneous T-Cell Lymphoma epidemiology-based market forecast report includes a comprehensive understanding of these market drivers and how they will impact the overall CTCL market size from 2019 to 2032, segmented into 7MM [the United States, the EU-4 (Italy, Spain, France, and Germany), the United Kingdom, and Japan].

Key Takeaways from the Cutaneous T-Cell Lymphoma Market Report

As per DelveInsight estimates, the total incident population of CTCL in the 7MM comprised of approximately 5,000 cases in 2022 and are projected to increase during the forecast period.

As per DelveInsight estimates, in 2022, gender-specific CTCL cases for males and females accounted for approximately 2,000 and 1,500 cases respectively in the United States. It is projected that these cases may increase during the forecast period.

Among EU4 and the UK, Germany has the maximum revenue share in 2022 while Spain has the lowest market share.

CTCL companies including Citius Pharmaceuticals (I/ONTAK), Soligenix (HyBryte), 4SC AG (Resminostat), Innate Pharma (Lacutamab), Codiak (exoIL-12), and others are evaluating their lead candidates in different stages of clinical development. They aim to investigate their products for the treatment of CTCL.

Cutaneous T-Cell Lymphoma Market Dynamics

The cutaneous T-cell lymphoma market dynamics reflect a landscape of evolving treatment options and a growing emphasis on personalized medicine. As a rare type of non-Hodgkin lymphoma affecting the skin, CTCL presents a unique set of challenges and opportunities for pharmaceutical companies and healthcare providers alike. The market has seen a surge in research and development activities, aimed at introducing novel therapies with improved efficacy and reduced side effects.

With advancements in understanding the molecular pathways involved in CTCL, targeted therapies have gained significant traction in the market. This shift towards precision medicine has led to the development of drugs that specifically target the aberrant signaling pathways driving CTCL progression. Additionally, immunotherapies such as checkpoint inhibitors have shown promising results, further diversifying the treatment landscape. However, challenges persist in terms of patient access to these innovative therapies, reimbursement issues, and the need for greater awareness among healthcare professionals regarding early diagnosis and optimal management strategies. The CTCL market is poised for continued growth, driven by ongoing clinical trials, collaborations between academia and industry, and a concerted effort to improve patient outcomes through innovative treatments.

Download the report to understand which factors are driving CTCL market trends @ <u>Cutaneous</u> <u>T-Cell Lymphoma Market Insights</u>

Cutaneous T-Cell Lymphoma Treatment Market

Mycosis fungoides (MF) and Sézary syndrome (SS) are chronic conditions that are typically considered untreatable, but manageable. These diseases are usually not life-threatening. The main aims of treatment are to ease symptoms, achieve remission, and delay disease progression. Patients in the early stages often respond well to therapies targeting the skin alone, while those with more advanced stages might need a mix of skin-directed and systemic treatments, which are the standard approaches. Key players in the market include Mallinckrodt Pharmaceuticals, Valeant Pharmaceuticals, Kyowa Kirin, Citius Pharmaceuticals, Seagen, and others.

In 2006, ZOLINZA (vorinostat) received FDA approval for treating cutaneous T-cell lymphoma, especially when the disease persists or reappears after other medications. Then, in 2018, the FDA approved POTELIGEO (mogamulizumab-kpkc) injection for treating adult patients with Sezary Syndrome (SS) after they had undergone at least one previous systemic therapy. This marked the first FDA approval of a drug specifically for SS, and it is manufactured by Kyowa Kirin.

Diverse therapeutic methods and treatments can differ based on a range of factors, including the stage of the disease, the size of the tumor, the particular subtype of CTCL, the presence or absence of specific symptoms, the individual's age and overall health, and other relevant considerations. There is a broad array of treatment choices available for those with CTCL, such as topical chemotherapy, radiation therapy, photochemotherapy, retinoids (vitamin A derivatives), and chemotherapy. These treatment options might be employed individually or in various combinations.

Recent Developments in the Cutaneous T-Cell Lymphoma Market

In September 2023, Citius Pharmaceuticals announced that they have received additional guidance from the US FDA regarding the planned resubmission of the Company's BLA for LYMPHIR (denileukin diffitox) for the treatment of patients with relapsed or refractory CTCL after at least one prior systemic therapy.

Emerging Cutaneous T-Cell Lymphoma Therapies and Key Companies

Some of the drugs in the CTCL pipeline include I/ONTAK (Citius Pharmaceuticals), HyBryte (Soligenix), Resminostat (4SC AG), Lacutamab (Innate Pharma), exoIL-12 (Codiak), and others.

Citius Pharmaceuticals' I/ONTAK (E7777) represents a refined version of denileukin diftitox (ONTAK), an earlier FDA-approved cancer immunotherapy designed to address persistent or recurring CTCL. E7777, a fusion protein, merges the interleukin-2 (IL-2) receptor-binding segment with fragments of diphtheria toxin. ONTAK was available in the US market from 1999 to 2014, after which it was voluntarily withdrawn. Enhancements in manufacturing led to a new iteration with the same amino acid sequence but notable improvements in purity and effectiveness. This updated version obtained regulatory clearance in Japan in 2021 for treating CTCL and PTCL.

In July 2022, Citius Pharmaceuticals conducted a Type B pre-BLA meeting with the US FDA to explore I/ONTAK (denileukin diftitox) for individuals facing persistent or recurrent CTCL. E7777 received Orphan Drug Designation from the FDA for PTCL in 2011 and for CTCL in 2013. The medication has successfully concluded its Phase III trial for patients dealing with persistent or recurrent CTCL. In September 2023, the company disclosed that they have acquired further directives from the US FDA concerning their intended resubmission of the BLA for LYMPHIR (denileukin diftitox) to treat patients with relapsed or refractory CTCL after at least one prior systemic therapy.

Soligenix is working on HyBryte, also known as SGX301 or synthetic hypericin, to treat CTCL. This innovative therapy, a pioneer in its class, employs safe, visible light for activation in a process called photodynamic therapy. Its key component is synthetic hypericin, a powerful photosensitizer applied directly to skin lesions and triggered by visible fluorescent light. In April 2021, the US FDA conditionally approved HyBryte as the proposed brand name for SGX301. Soligenix plans to submit a new drug application (NDA) for HyBryte's authorization for CTCL treatment to the FDA in the latter part of 2022, with potential FDA approval expected in the second half of 2023. The company also aims to submit a Marketing Authorization Application (MAA) to the EU for CTCL treatment by the first half of 2023. Having successfully completed its

Phase III trial, Soligenix faced a setback in February 2023 when the US FDA issued a refusal to file Letter for HyBryte's New Drug Application in CTCL treatment. Recently, in April 2023, the company submitted a request for a Type A Meeting with the US FDA to formally discuss the design of a second Phase III study to evaluate HyBryte in early-stage CTCL treatment. According to the company's latest update, the first Phase III study yielded positive and statistically significant results, and Soligenix is actively collaborating with the FDA to plan the next confirmatory Phase III study.

The other therapies in the CTCL pipeline include

Resminostat: 4SC AG

Lacutamab: Innate Pharma HemaMax: Libo Pharma

The anticipated launch of these emerging therapies for CTCL are poised to transform the market landscape in the coming years. As these cutting-edge therapies continue to mature and gain regulatory approval, they are expected to reshape the CTCL market landscape, offering new standards of care and unlocking opportunities for medical innovation and economic growth.

Discover more about drugs for CTCL in development @ <u>Cutaneous T-Cell Lymphoma Clinical</u> Trials

Cutaneous T-Cell Lymphoma: Overview

Cutaneous T-cell lymphoma (CTCL) comprises a set of conditions characterized by the abnormal buildup of malignant T-cells in the skin, potentially leading to the emergence of rashes, plaques, and tumors. More than three-quarters of diagnosed skin lymphomas are CTCLs, often manifesting as skin rashes resembling eczema, with the capacity to affect broad areas of the body. Typically falling under the indolent (chronic) lymphoma category, most CTCLs are treatable yet incurable, generally not posing an immediate threat to life. Various types of cutaneous T-cell lymphoma exist, with mycosis fungoides being the most prevalent. Sezary syndrome, a less common form, induces widespread skin redness. While some types of CTCL, like mycosis fungoides, progress slowly, others exhibit more aggressive behaviors.

The exact cause of cutaneous T-cell lymphoma remains unknown. Broadly, cancer initiates when cells undergo DNA mutations, resulting in an excess of abnormal T-cells that target the skin. Symptoms of CTCL encompass the formation of skin patches and nodules, swollen lymph nodes, hair loss, thickened skin on the hands' palms and feet soles, and a rash-like, intensely itchy redness spanning the entire body.

Cutaneous T-Cell Lymphoma Epidemiology Segmentation

The CTCL epidemiology section provides insights into the historical and current CTCL patient

pool and forecasted trends for individual seven major countries. It helps to recognize the causes of current and forecasted trends by exploring numerous studies and views of key opinion leaders.

The CTCL market report proffers epidemiological analysis for the study period 2019–2032 in the 7MM segmented into:

Incident population of CTCL
Type-specific Cases of CTCL
Sub-type specific incidence of CTCL
Gender-specific cases of CTCL
Stage-specific cases of CTCL
Treatment-eligible incident population in early and advanced stage

Scope of the Cutaneous T-Cell Lymphoma Market Report

Cutaneous T-Cell Lymphoma Therapeutic Assessment: Cutaneous T-Cell Lymphoma current marketed and emerging therapies

Cutaneous T-Cell Lymphoma Key Companies: Pfizer, Eisai, Citius Pharmaceuticals, Bristol Myers Squibb, Merck, Kyowa Kirin, Medivir, Seagen, Soligenix, 4SC AG, Galderma, Equillium, Innate Pharma, BeiGene, Codiak BioSciences, Astex Pharmaceuticals, and others

Cutaneous T-Cell Lymphoma Pipeline Therapies: SGX301, Pembrolizumab, CD11301, EQ101, Tolinapant (ASTX660), exoIL-12, Lacutamab, Remetinostat, Resminostat, Tislelizumab (BGB-A317), and others

Cutaneous T-Cell Lymphoma Market Dynamics: Attribute Analysis of Emerging Cutaneous T-Cell Lymphoma Drugs

Competitive Intelligence Analysis: SWOT analysis and Market entry strategies Unmet Needs, KOL's views, Analyst's views, Cutaneous T-Cell Lymphoma Market Access and Reimbursement

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About DelveInsight

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Cutaneous T-Cell Lymphoma Pipeline Report

Cutaneous T-Cell Lymphoma Pipeline Insight – 2024 report provides comprehensive insights about the pipeline landscape, including clinical and non-clinical stage products, and the key CTCL companies, including Wellness Pharma, Seagen, Soligenix, 4SC AG, among others.

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