

## EYE TREATMENT

# Reliance Life readies stem cell therapies

BY SEEMA SINGH  
*seema.s@livemint.com*

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MUMBAI

Seven years after its inception amid much fanfare, Reliance Life Sciences, or RLS, is finally rolling out stem cell-based therapies in India, beginning with a treatment that can restore or improve vision.

“This is the first commercial stem cell treatment in ophthalmology in the country,” said K.V. Subramaniam, CEO and president, RLS, part of the

Mukesh Ambani-led Reliance group. The company, which has invested around Rs1,000 crore in the business, has lined up other stem cell therapies for cardiac infarction, diabetic ulcer, and stable vitiligo or leukoderma (a skin disease), among others, to be offered in clinics in the next few months. The aim is to break even by next year, said Subramaniam.

For the eye treatment, RLS uses cells from the limbus—the

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junction between the cornea and conjunctiva which is rich in corneal stem cells—to restore or improve vision in people whose cornea has been damaged by a burn or an accident. After clinical trials at the All India Institute of Medical Sciences in New Delhi and Aditya Jyot Eye Hospital in Mumbai, RLS has begun offering the treatment in these two cities through ophthalmologists. “We intend to reach all eye hospitals in the country within a year,” said Subramaniam.

It’s a fairly centralized model of delivery which is intended to reach all corners of the country. The RLS cell processing facility in Mumbai, with cGMP (global standard in good manufacturing practices) certification, will receive the limbal biopsy of the patient, excised from the normal eye. Stem cell grafts will then be created and sent back for transplantation to the eye surgeon treating the patient, who, RLS claims, will be trained for such surgeries.

A similar model will be adopted for cardiac treatments where RLS has completed clinical trials at Madras Medical Mission in Chennai, with “formal regulatory approval”, using mesenchymal stem cells derived from the patient’s own bone marrow.

Several groups in India and overseas are harvesting adult stem cells to grow tissues of various organs such as heart, brain, liver, and skin, but most of these efforts are in experimental stages. Ophthalmology remains at the forefront of application. On 25 June, pharmaceutical firm **Pfizer Inc.** announced an investment of \$3 million (Rs13 crore)

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**K.V. Subramaniam**  
CEO, Reliance Life Sciences

in a San Diego-based stem cell start-up EyeCyte which is developing treatments for eye diseases, including diabetes-induced retinal damage.

“I don’t know what technique RLS is using but I assume it’s similar to ours which, I think, is not ready for mass-scale application,” says Virendar Sangwan, eye surgeon at Hyderabad-based LV Prasad Eye Institute, or LVPEI, who has pioneered corneal regeneration using limbal stem cells and is part of the most prolific team in this procedure anywhere in the world. LVPEI recently secured grants from the department of biotechnology under the Indo-Canadian and Indo-Australian bilateral programmes to “refine” its stem cell technology and scale it up for large-scale applications.

Sangwan, who has more than 500 such surgeries to his credit, says the “quantification of the stem cells is not yet perfected”. “There aren’t any objective parameters to test if the grown cells are good enough”, he adds. RLS, however, says, that along with the product, it has developed the necessary protocol for administering it and sees no

problem with autologous transplants (from a patient’s own cells). But it’s concerned about allogenic therapy where stem cells from related donors are used to grow the grafts, even though the company is about a year away from offering that.

“There needs to be more clarity in regulatory procedures when it comes to allogenic treatment,” says Subramaniam. Referring to sporadic “investigator-initiated” claims of stem cell success stories in the country, he says “nobody asks if that’s due to a natural healing process or the placebo effect”. The placebo effect refers to an accepted medical phenomenon where people treated with placebos (or medicines that have no bearing on their condition) respond to it simply because they believe the treatment will improve their condition.

Regulatory grey areas seem to haunt the industry. Bangalore-based Stempeutics Research Pvt. Lab, part of the Manipal Education and Medical group, says it would go to Malaysia, where it has set up a subsidiary, for allogenic studies if the approvals don’t come on time.

The industry’s impatience is riding the phenomenal growth in the stem cell product and services market, which research firm ReserachAndMarkets projects, will grow from \$24.6 billion (Rs1.07 trillion then) in 2005 to \$68.9 billion in 2010.

For RLS, stakes are particularly high as the company is trying hard to live up to initial expectations generated worldwide after the George Bush administration, in 2001, included RLS stem cell lines in the list of approved ones which would be eligible for US stem cell federal funding.

Today, the company plans to make India a springboard to launch its offerings in the US and European markets, where it is suitably aided by its businesses in clinical services and biopharmaceuticals.