

# ICX-RHY



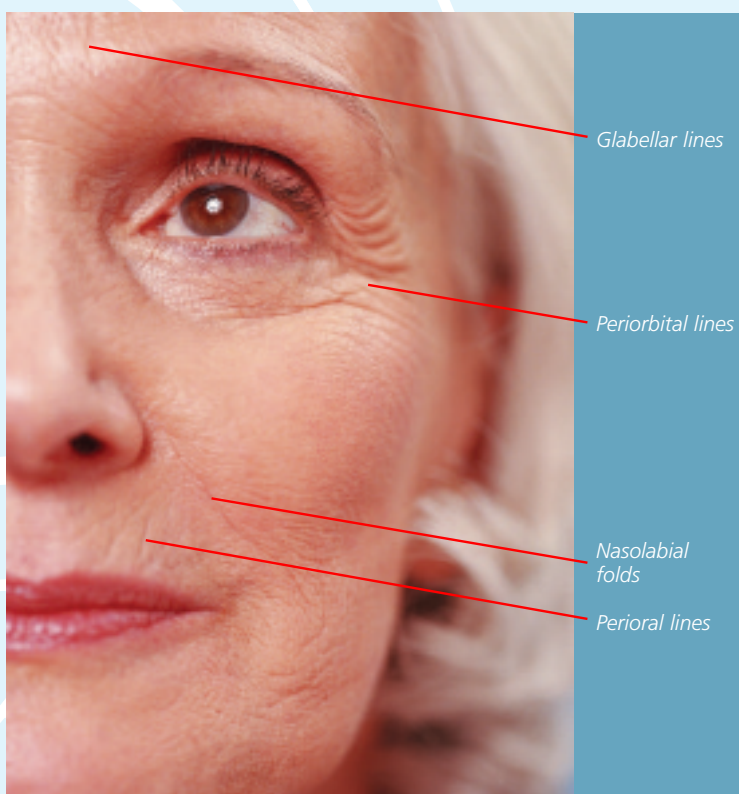
Intercytex

PIPELINE	Preclinical	Phase I	Phase II	Phase III	Market
ICX-RHY					

ICX-RHY is a novel facial rejuvenation product designed to enhance the skin's collagen support matrix, thus enabling the appearance of facial wrinkles and folds to be improved. It aims to provide a more youthful appearance, helping to combat the cosmetic effects of ageing.

ICX-RHY comprises allogeneic, collagen-secreting human dermal fibroblasts (HDFs) presented in a sterile suspension. It is injected intradermally directly into the affected area using local anaesthesia. Each injection delivers a minute volume of ICX-RHY; the procedure is straightforward and minimally invasive. The benefit is expected to become apparent once HDFs have begun to lay down collagen within the dermis; this effect is expected to be sustained, providing long-term enhancement of the subject's facial appearance. It is anticipated that repeat administrations may be given as required.

Once approved, it is envisaged that ICX-RHY will be administered by cosmetic surgeons, dermatologists and other healthcare professionals specialising in facial wrinkles. ICX-RHY will be supplied directly from the company's manufacturing facility in Manchester. It is straightforward to administer and requires only standard storage conditions prior to use.



Potential treatment sites for ICX-RHY.

## Key Terms

**Allogeneic cells** are sourced from an unrelated donor.

**Collagen** is a tough, insoluble protein found throughout the body in the connective tissues that holds muscles and organs in place. In the skin, collagen supports the epidermis, making it durable and elastic.

**Dermal rhytids** are commonly known as wrinkles; these are creases, often deep, formed in the skin due to age, stress, sun damage and other factors.

**Human dermal fibroblasts** (or HDFs) are the principal cell type found in the dermal layer of human skin where they secrete collagen, the main component of the dermis. (The dermis is a layer of skin just underneath the epidermis that contains sensitive nerve endings, blood vessels and hair follicles.) Forming a meshwork of fibres, collagen is key to the structure and texture of skin.

**Allogeneic HDFs** are derived from the dermis of normal human skin.



### Skin Physiology

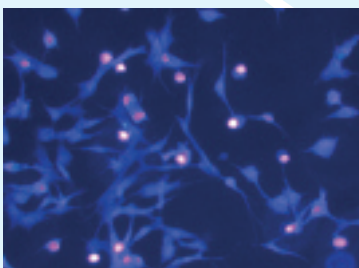
Wrinkles occur in particular locations on the face, neck and hands in response to repeated muscular action or the sagging of ageing skin under the force of gravity or excessive exposure to the sun, heat and cold and chemical agents present in the environment. Wrinkles are often present in areas of particularly thin skin such as around the eyes (periorbital folds) between the side of the nose and corners of the lips (nasolabial folds) or between the eyebrows (glabellar folds).

### Market Opportunity

The market for cosmetic procedures is growing strongly. There are around 1.1 million soft tissue filler procedures performed each year in the US, excluding Botox®, which adds a further 1.9 million patient visits. The overall market is growing at 8% per annum. (American Society of Plastic Surgeons).

### Clinical and Commercial Development

A Phase I trial, conducted in collaboration with Professor Nick Lowe MD FRCP at the Cranley Clinic, London, consisting of a placebo-controlled safety and tolerability study in 10 healthy volunteers has been completed. Each subject received a course of three injections given into the skin of the upper arm. ICX-RHY was shown to be very well tolerated; no serious adverse events were reported and all adverse events were transient and resolved without treatment. Intercytex is now seeking regulatory approval for a Phase II trial, expected to begin during the first quarter of 2007. The proposed Phase II trial will evaluate the efficacy of ICX-RHY when injected into facial wrinkles. It is anticipated that preliminary results from this trial will be available around the middle of 2007. Additional Phase II trials are being planned for other types of wrinkles and scars.



*Human dermal fibroblasts*

Intercytex will develop ICX-RHY through all stages of clinical development and registration to launch and may utilise similar distribution channels to ICX-TRC. Intercytex will manufacture ICX-RHY for Europe and the US at its GMP manufacturing facilities.

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