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Dyve Biosciences

Dyve is an R&D biopharmaceutical leader creating disruptive innovations through our unique transdermal delivery technology



 Human proof of concept in multiple patients in multiple indications, and a vast library of potential drug candidates in therapeutic and aesthetic indications. For example,

Adipolysis

Melasma/dyschromia

Alopecia

Erythema

Analgesia

Gout

Antifibrinolytic

Rhytids

Advanced clinical programs in gout and melasma,
 both with anticipated phase 2 trials in 2020

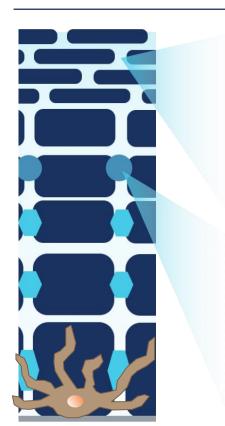
Mechanism of Action: Dyve Technology opens two key transdermal doors, the stratum corneum lipid matrix and tight junctions

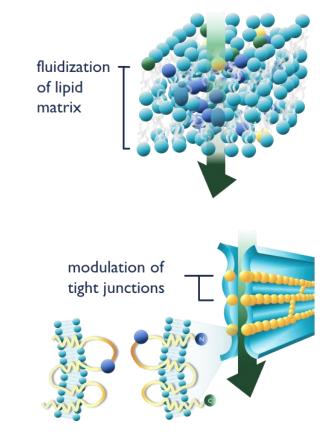
Skin Barrier

Dyve Technology

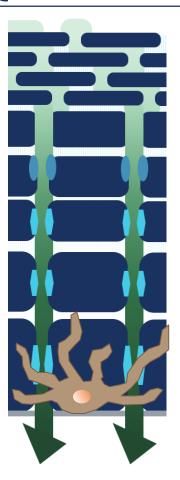


Opening Physiologic "Valves"

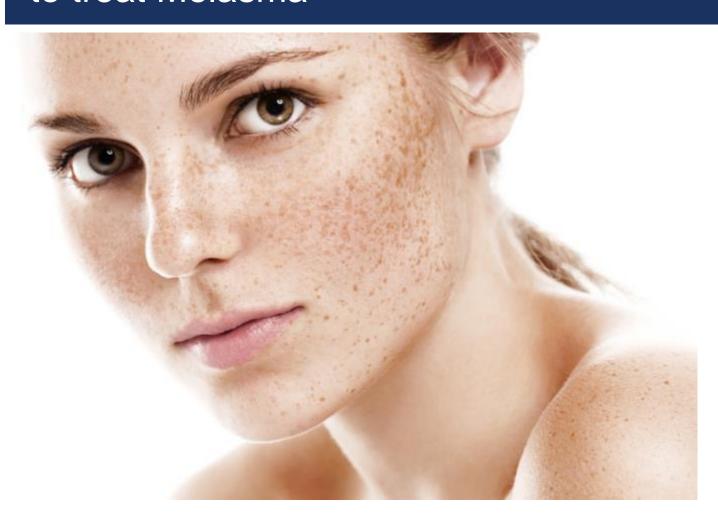








DYV600 – Tranexamic acid in a novel transdermal delivery system to treat Melasma

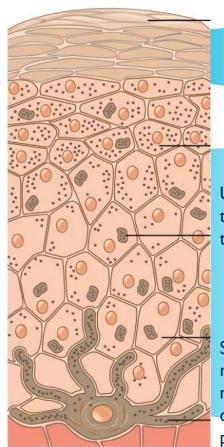


 High prevalence – 50-70% of post-partum women with melasma, even larger when considering broader dyschromia

Unmet Need

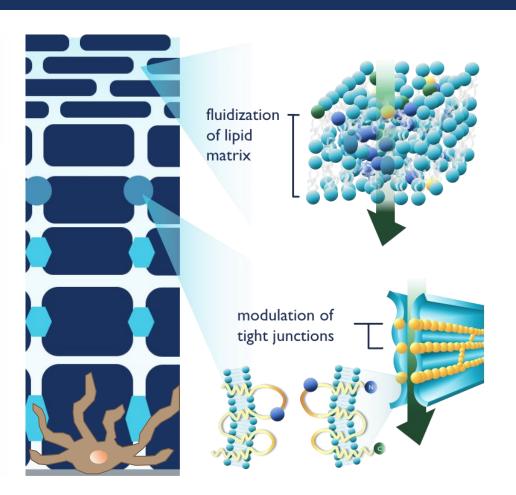
- Modest efficacy of existing topical options
- Lack of effective, safe, chronic use topical
- Safe drug with observed efficacy when delivered acutely delivery orally or by injection for antifibrinolysis
- Dyve technology takes oral or injected drugs and optimizes their delivery transdermally

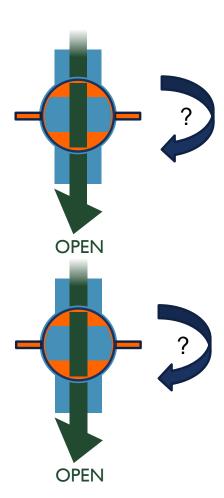
DYV-600: Targeting Melasma at the Source



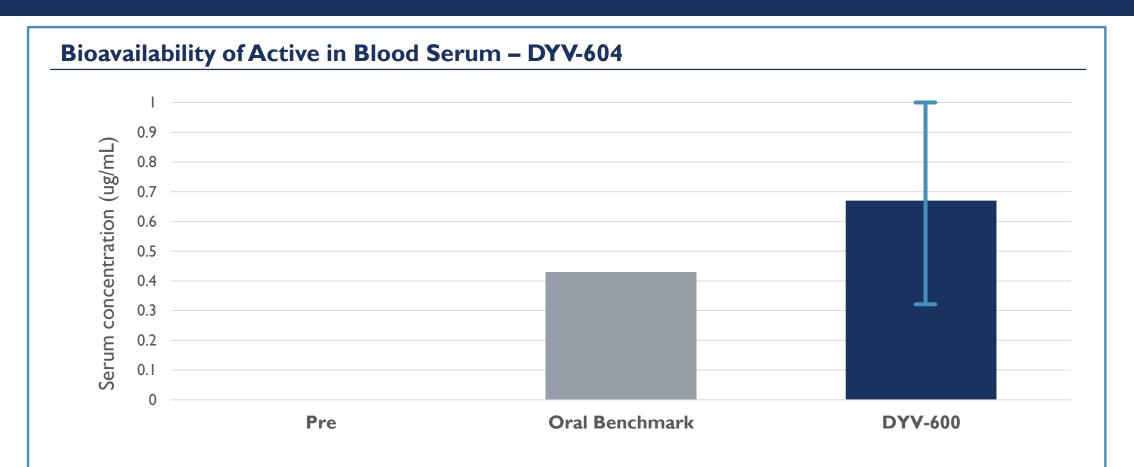
Uneven pigmentation is the result of melanosomes that rise to the surface.

Shutting off the process requires treating deep melanocytes – beyond current topicals' penetrating ability.





DYV-603: Bioavailability – Summary of Results



Blinded testing (n=3). Subjects applied 0.5 mL of Dyve Tranexamic acid cream (6% active) every 2 hours for 8 hours (total of 5 doses) for a total of 125mg (average of ~1.5mg/kg). Blood drawn 1 hour after final dose. Serum tested for concentration of active molecule and compared to baseline concentration (pretreatment). Oral dose equivalent benchmark calculated from Pilbrant, et al, doi:10.1007/bf00554669

DYV-600: Overview of Melasma Clinical Programs

DYV-601: Feasibility

Open label feasibility in treatment resistant patients.

DYV-602: Split–face Versus 4% Hydroquinone (HQ)

Randomized, double-blind, head-to-head, split-face study comparing tranexamic acid in a novel transdermal delivery system to hydroquinone for improvement of melasma.

DYV-603: Split–face with/without Turnover Agents

Randomized, single-blind, split-face study evaluating tranexamic acid in a novel transdermal delivery system, alone or with skin turnover agents, for improvement of melasma.

DYV-604: Full-face comparing various technology formulations (on-going)

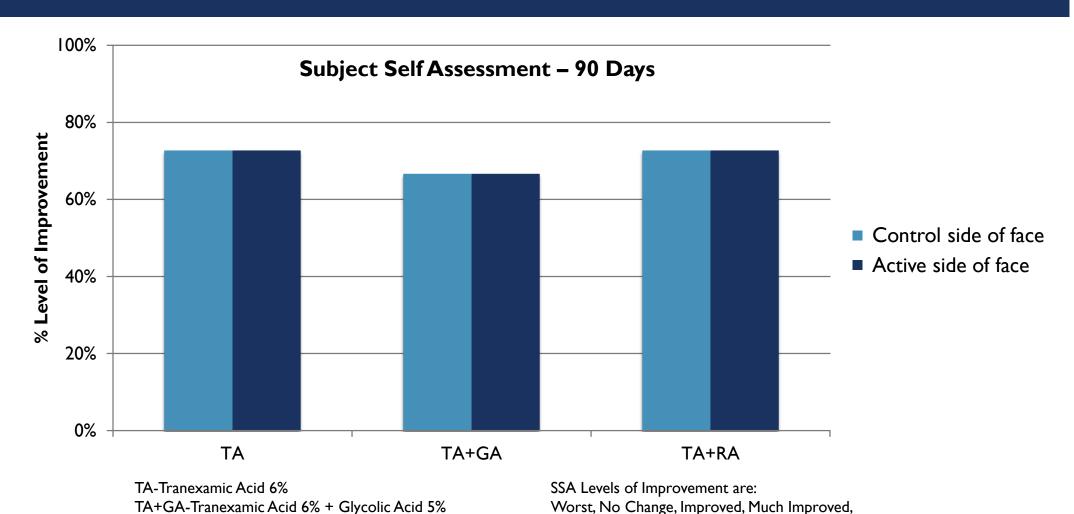
Randomized, double-blind, placebo controlled, parallel group design.

DYV-601: Feasibility Study Showed Rapid Resolution of Treatment Resistant Melasma



DYV-603: Due to bioavailability, both sides respond in a split-faced study design

TA+RA-Tranexamic Acid 6% and Retinoic Acid 0.25%



and Very Much Improved.

DYV-603: Representative Subjects – Non Active *Control* Side



DYV-604: Interim Patient Data – 60 Days





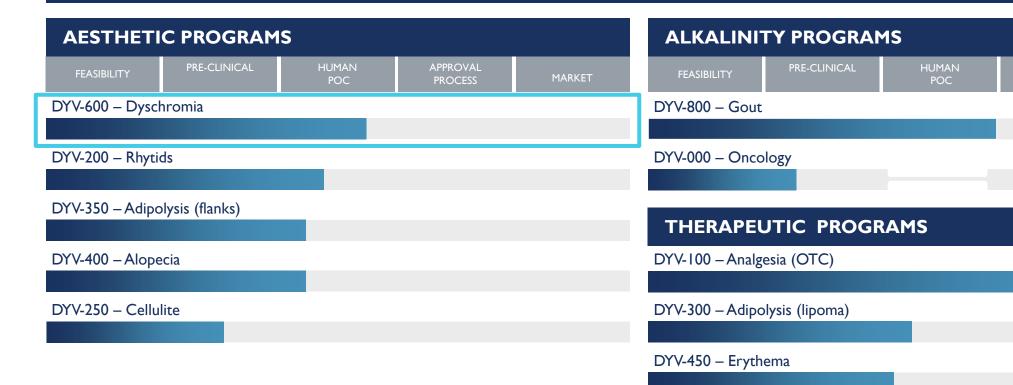
Randomized, Double-Blinded, Placebo Controlled Efficacy and Safety Study of a Transdermal Treatment for Melasma (n=36). Subject applied 1.2mL DYV-600 to face b.i.d.

Investigators:

- Mitch Goldman, MD
- Sabrina Fabi, MD
- Rosalyn George, MD
- Joel Cohen, MD
- John Joseph, MD

Data read-out 2H 2019

Dyve's Strong R&D Pipeline





APPROVAL

PROCESS



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