Clopidogrel for the Treatment of FSGS

(Focal Segmental Glomerulosclerosis)

Delta4 – Asset out-licensing opportunity

Confidential | Non-binding

FSGS at a glance

- A heterogeneous group of different etiologies with defined glomerular histopathology
- Significant risk for end-stage-kidney disease
- High rate of steroid resistance and recurrence after kidney transplantation
- Limited effective targeted therapies

Clinical Gap

- Current treatments are largely non-specific (steroids, immunosuppressants)
- Significant side-effect burden
- Clear need for safer, mechanism-based options

Asset: Clopidogrel (repurposed) for FSGS

Indication: Primary and secondary FSGS

Development Stage: Preclinical efficacy demonstrated

Route of Administration: Oral

Positioning: Disease-modifying, low-cost, repurposed therapy

DIFFERENTIATION HIGHLIGHTS

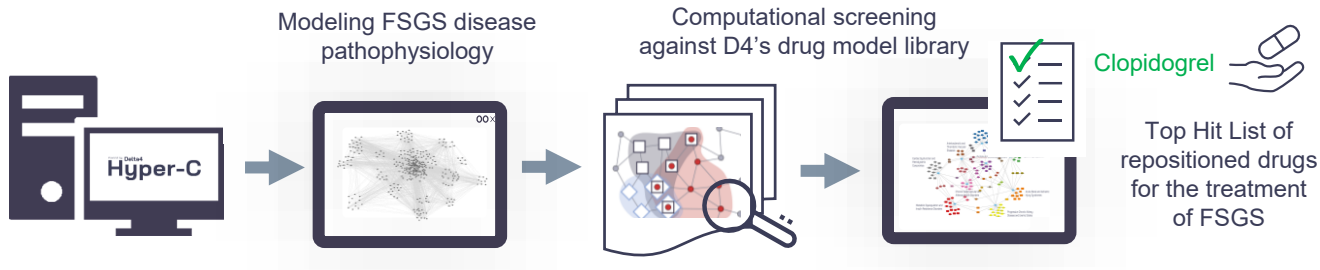
- Known human safety profile
- Rapid path to clinic
- Potential for orphan drug positioning

Full pre-clinical report available | Phase II Study Plan available: *Kidney Int Rep. 2023 9(2):478-481*

Discovery Approach

Transl Res. 2023 259:28-34

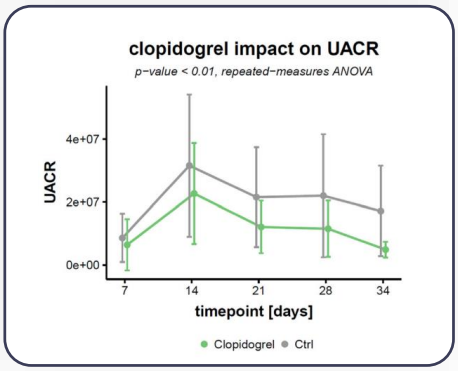
Systems biology–based screening using Delta4's proprietary AI-supported Hyper-C platform. Target–pathway–drug matching across disease-relevant networks.

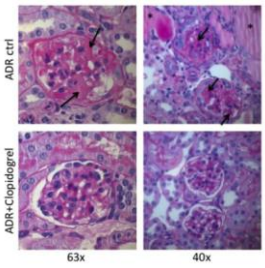


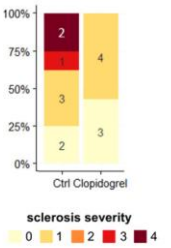
Key Findings, Animal Models

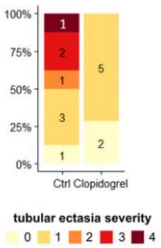
- Clopidogrel inhibits key disease modifying players such as TGFB1, TNF, SERPINE1, RHOA, CD40LG, and P2YRY12
- Clopidogrel activates the two renoprotective molecules NFE2L2 and PRKAA1
- Clopidogrel has anti-inflammatory and anti-fibrotic potential in FSGS disease development and progression
- Clopidogrel may exert its effect on top of standard of care

Clopidogrel strongly modulates FSGS-relevant pathways









- Significant improvement of albuminuria and renal histopathology in mouse FSGS models
- Reduction in glomerulosclerosis and tubular damage

Transl Res. 2023 259:28-34

External Validation & Clinical Logic

Independent Supporting Evidence

- Literature supports antiplatelet agents for chronic kidney disease (CKD).

Cochrane Database Syst Rev. 2022 2(2):CD008834

- P2Y12 is expressed in the kidneys of patients with CKD, correlates with eGFR and can be blocked by clopidogrel, preserving kidney function in CKD.

Mol Ther. 2022 30(9):3017-3033

Clinical Development Concept

- Repurposing-driven Phase II proof-of-concept study
- Proteinuria reduction as primary endpoint
- Focus on steroid-resistant or refractory population

Competitive Differentiation

- Oral small molecule
- Established manufacturing and supply chain
- Lower development risk vs. novel chemical entities

Patent Estate

- Granted patents covering the use of clopidogrel in FSGS
- Protection across multiple key territories
- Includes method-of-treatment claim for clopidogrel in FSGS

Patent details available via The Lens (lens.org): EP 4255427 A1

Patents Granted

Jurisdiction	Registration No.	Priority Date
Europe (EP)	21820615.9	03.12.2021
Spain (ES)	4255427	03.12.2021
United Kingdom (GB)	4255427	03.12.2021
South Africa (ZA)	2023/06132	03.12.2021
Submitted U.S.A.	18265233	03.12.2021

Out-licensing opportunity

Delta4 is offering this asset for out-licensing. This opportunity provides partners with a de-risked, clinic-ready program, supported by strong mechanistic rationale and a clearly defined, executable development path.

Contact

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