



## Aptuit Verona

### FACTSHEET



#### Aptuit's New Acquisition

Aptuit's acquisition of GlaxoSmithKline's Medicines Research Centre in Verona, Italy expands and bolsters Aptuit's integrated scientific capability and expertise for the benefit of our customers globally.

#### Aptuit Verona

We recognize the scientific expertise of Verona's employees and will continue to develop the exceptional talent base which includes 500 highly-skilled drug development experts, all of whom have long-standing scientific expertise and specialized knowledge of integrated drug discovery and development programs, as well as a unique understanding of indication-specific drug discovery.

The Verona facility houses state-of-the-art equipment and scientific tools that will enhance Aptuit's ability to continually offer the best science, service, and people in the industry to our clients. In addition, the site has a world class reputation for neurological discovery and development as well as cardio vascular and anti-infectives experience.

By broadening our geographical base to Italy, we are continuing to build our global presence through an integrated network of facilities, depots, and strategic hubs to better serve our clients.

#### Increased Service and Product Offerings

Since Aptuit's inception, we have built a world-class, integrated drug development organization. This acquisition not only builds and strengthens our offering in key scientific services, but also extends the range of our offering into drug discovery and clinical trial design and management as part of our company's strategic growth plan.

#### Services available at our Verona facility include:

##### Discovery Services

###### Target Discovery and Biology

- Target distribution
- Target functional characterization
- Electrophysiology in cells and integrated systems
- Native tissues, cell lines and primary cells
- Animal model development
- Range of validated CNS models

##### Lead Characterization & Screening

- High Throughput Screening
- Selectivity and Liability screening
- Virtual screening and library design
- Reagent generation and assay development
- Functional and binding assays
- Lead pharmacological profiling (in recombinant, native and in-vivo models)
- PK/PD analysis
- Translational biology

##### Medicinal Chemistry

- Computational chemistry
- Rational drug design
- Structure-activity relationship
- Array synthesis
- Synthesis of discrete compounds

##### Lead Characterization & Screening

- Structural characterization of complex molecules
- Screening of physicochemical properties

##### Integrated Lead Optimization

- Group of highly integrated disciplines (Medicinal Chemistry, Biology, Discovery DMPK) with a solid track record of delivery of high quality candidates
- Group at the cutting edge in understanding causes of attrition and applying the most advanced approaches to reduce it

##### Safety Assessment

- Early screening of toxicity, including in silico prediction
- Toxicity studies (GLP) up to 6 months
- Safety Pharmacology studies (GLP) including Abuse Liability Assessment and Neuro-Cardio models
- Integrated investigative capabilities, including biomarkers identification and validation
- Regulatory and Investigative Pathology, including electromicroscopy (GLP), animal model characterization, transgenic phenotyping and peer-review
- Non Clinical Assessment of Safety and regulatory document preparation

##### DMPK and Bioanalysis

- In-vitro High Throughput Assays
- Preclinical and clinical blood, plasma, and tissues bioanalysis
- Metabolic profile in plasma, tissues excreta and in-vitro preparations
- Structural identification and characterization of metabolites
- ADME in-vitro and in-vivo
- IVIVE, mechanistic PK/PD analysis, Toxicokinetics, TK modeling
- GLP/non-GLP options



### Laboratory Animal Science

- Animal model development
- Range of validated CNS models
- Genetically modified mouse models: colony maintenance and phenotyping

### Development Services

#### API Synthesis and Development

- Discover and develop innovative, cost-effective, “green” and well-understood chemistry for the manufacture of API and selection of version, form and particle size
- Develop analytical methods and provide analytical data to guide synthetic route development and devise an appropriate analytical control strategy for the manufacturing of pharmaceuticals
- Supply API batches to support the product development
- Facilities to manage highly potent compounds
- Deliver to (primary) manufacturing robust chemical processes and analytical methods (including QbD approach and PAT utilization) for the successful production of API batches
- Deliver all required reference standards (analytical standards, impurities, degradants, metabolites, isomers)
- GMP manufacturing facilities

#### Pharmaceutical Development

- Design, development and optimisation of dosage forms (formulations and processes) for preclinical/clinical investigations
- Application of simple formulation approaches and straightforward manufacturing processes in early phases
- Understanding of the biopharmaceutics of oral dosage forms applying in-silico/in-vitro tools in combination with pre-clinical and clinical PK data evaluation
- Dosage Form Development: Liquid: Oral liquids (solutions, suspensions, emulsions); Solid: Capsules (hard capsule shell) filled with granules or powder, Tablets (immediate release, modified release), lyophilized powder, micro and nano – milled powder in Spray Dried formulations; semisolid: aqueous /lipid suspensions, micro and nano – milled suspensions, hot melt
- Provision of clinical supplies including manufacturing of intermediate bulks and primary packaged materials
- Identification of Critical Quality Attributes (CQAs), Critical Process Parameters (CPPs), and Source of Variability via data trending tools, multivariate statistical analysis and risk assessment

- Specialized analytical capabilities delivering a complete package of services including streamlined method development and validation, applying QbD
- Solid state characterization to support drug development from API isolation step to final product manufacturing
- Degradation chemistry studies on API and Drug Product and genotoxic risk assessment
- Design, management and evaluation of forced degradation and stability studies for both drug substances and drug products
- CMC data preparation to support international regulatory submissions for early and late clinical phases (Europe, US, Canada, Rest of the World)
- GMP manufacturing facilities for oral dosage forms equipped with barrier technology for highly potent compounds

#### Clinical Services

- Design and implementation of clinical plans up to Phase II
- Design, management, analysis and interpretation of clinical pharmacology studies
- Design, management, analysis and interpretation of Phase II clinical studies
- Data Management
- Statistical analysis and interpretation
- Clinical Pharmacokinetic analysis and interpretation
- Pharmacometrics services
- Modelling and Simulation
- Translational Medicine
- Experimental Medicine

#### Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, clinical packaging and logistics, and clinical support services, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit’s services, please call or email:

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**Engineering a better drug development  
process through scientific excellence.**