**For Immediate Press Release**

# GVK Bioscience's Ahmedabad Clinical Pharmacology Unit successfully clears the USFDA Audit

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Hyderabad, July 30 2012: GVK Biosciences, Asia's leading Contract Research Organization today announced that its Ahmedabad Clinical Pharmacology Unit successfully cleared the US FDA Audit with zero 483s/observations from the agency. USFDA visited and audited a First-to-File study for one of GVK BIO's customers.

The GVK BIO Ahmedabad facility, commissioned in 2010, has 3 clinics with 110 beds. The facility has been inspected and approved by Drugs Controller General of India (DCGI), ANVISA-Brazil and Ministry of Health (MoH)-Turkey. The Ahmedabad facility carries out Bioavailability and Bioequivalence (BA/BE) studies that are submitted to various regulatory agencies including FDA, TGA (Australia), European Regulatory agencies, Health Canada, ANVISA-Brazil and MoH (Turkey).

Manni Kantipudi, Chief Executive Officer, GVK BIO said "This is a clear testimony of the high standards of quality and processes followed at GVK BIO. The Sponsor can now carry out BA/BE studies at either of our sites, Ahmedabad or Hyderabad, with a wider choice of population and capacities". The Ahmedabad clinical facility has the capability to execute BA/BE studies in healthy human volunteers, in special populations and can conduct some patient based studies.

The Ahmedabad success comes on the heels of regulatory joint inspection by FDA, ANSM (France), AGES (Austria) and WHO, of the GVK BIO Hyderabad facility. This inspection was the first joint inspection of a CRO by the four agencies. GVK BIO received zero 483s by FDA in this joint inspection. The GVK BIO Hyderabad facility is a full service provider of BA/BE services with 4 clinics and 144 beds supported by a bioanalytical facility with 16 LC-MS/MS machines. The Hyderabad facility has been inspected and approved by various regulatory agencies like DCGI, ANVISA-Brazil, MoH (Turkey), FDA, AFSSAPS (France), WHO and MHRA.

**About GVK BIO Clinical Pharmacology Unit**
Established in 2003, the GVK BIO Clinical Pharmacology Unit (CPU) supports Generic and NCE Drug Development with the conduct of Bioequivalence/Bioavailability studies. We have completed 750+ studies including those for global regulatory submissions.

**About GVK Biosciences**
GVK Biosciences (GVK BIO) is Asia's leading Contract Research Organization. With a vision to be a global leader in life sciences research and services, GVK BIO offers a spectrum of stand-alone and integrated services across the life sciences R&D value chain. Our discovery services consist of Analytical Services,

Chemistry Services, Biology and Informatics, while the Development Services include Clinical Research, Medical Affairs, Clinical Pharmacology, Analytical Development, Process R&D, Custom Synthesis and Contract Manufacturing. GVK BIO's diverse portfolio of nearly 200 customers includes some of the world's largest pharmaceutical, biotechnology, agro, life-sciences companies and leading academic institutions. Please visit us at www.gvkbio.com to know more.

***For any further information, please contact:***
Sharada Alvakonda
Dy General Manager – Corporate Communications
GVK Biosciences Private Limited
T 0091 40 66929999
E sharada@gvkbio.com

Notes for the Editors:
First-to-file Studies: With a first-to-file status comes a 180-day marketing exclusivity (from the date of approval of the ANDA), during which the FDA may not approve another ANDA for such generic product. During this period, the first-to-file generic company can reap huge profits on the sale of the generic drug before other generic equivalents enter the market following the expiration of the 180-day exclusivity period.