CURRICULUM VITAE

Donald D. Banerji, MD, FAAAAI

Clinical development professional with 33 years of global clinical research and development experience (Phase I-IV) in the pharmaceutical industry. Recently retired from Novartis as Global Clinical Development Head of Respiratory and Allergy Medicine. Recognized by peers and external scientific community as an expert in pulmonary and allergy drug development bringing several iconic brands to market with millions of patients benefitting from treatment through improving care and outcomes for patients with respiratory diseases. Managed multidisciplinary teams in the filing of several new drug applications. Responsibilities included strategic and tactical planning, regulatory interactions with global health authorities, appropriate resource and budgetary management and timely execution, approval of high-quality large drug development programs and delivery of groundbreaking data. These global programs over a span of 3 decades resulted in the approval and competitive labeling of 14 innovative medicines, including 3 inhaled steroids for asthma, a triple combination of 2 bronchodilator and an inhaled steroid for asthma, 3 non-steroidal inhaled controller drugs for asthma, 3 intranasal steroids for allergic rhinitis and 4 bronchodilator drugs for COPD. Signature achievements at Novartis included first to market with the development and approval of the first to market inhaled dual combination medicine in COPD (Ultibro) and the first to market triple combination medicine in asthma (Enerzair). With reimagining medicine as a core driver, these treatments changed the practice of medicine and were incorporated in global treatment guidelines for COPD and asthma. Recipient of numerous corporate awards including the highest scientific award of Distinguished Scientist 2016 for pioneering work in COPD. Published over 400 primary manuscripts and abstracts, including the landmark study FLAME in NEJM.

Professional Experience

Novartis Pharmaceuticals Corporation, East Hanover, NJ

Mar 2017-July 2021	VP, Global Clinical Development Head, Respiratory and Allergy
Mar 2008-Feb 2017	VP, Head Inhaled Portfolio, Respiratory Clinical Development

As Clinical Development Head (CDH) oversaw all global clinical development activities from Phase II to registration including appropriate external and internal insights, scientific interactions with Health Authorities (including preparation of high-quality briefing books) and external experts (at advisory board meetings) thus gaining alignment of drug development principles and strategy from the beginning with adherence to clinical governance principles and processes. As CDH, actively participated with many internal leadership teams including opportunities in early phase, commercial and business development to designing trials, provide strategic input, determine best value for in-licensing compounds and optimize probability of success. Led the Novartis team to defend and successfully negotiate approval of 2 asthma products at the EMA (CHMP) oral hearing. These registration programs recruited approximately 30,0000 patients and included some of the most innovative clinical trials (GLOW, IGNITE, PALLADIUM) for market access purposes to maximize unmet medical need, commercial value and challenge the status quo of global treatment guidelines. As example, in COPD, some of the trials went head-to-head versus the 2 standards of care, Spiriva® and Seretide® in COPD which led to new implementation/recommendations of GOLD global guidelines in the management of COPD (FLAME published in the NEJM). Designed innovative development programs in Asthma with over 10,000 patients leveraging data from early concepts and modeling to executing a state-of-the-art phase 3 program with evening dosing. Led to groundbreaking data and first to market approval and launch.

The filings and approvals of these respiratory products were done in the shortest time vs industry metrics

Sanofi Aventis Pharmaceuticals, Bridgewater, NJ

January 2005-March 2008 Executive Director, Pulmonary Therapeutic Area
International Clinical Investigations, Research and Development

KEY ACHIEVEMENTS

Submitted the complete response to the Approvable Letter for Alvesco"' (Ciclesonide) NDA in July 2007. Obtained approval on January 10, 2008.

Successfully designed and executed clinical studies in response to the FDA's Approvable Letter.

Collaborated in getting AlvescoTM approved in 45 countries ex-US. Obtained US approval on January 10th, 2008.

Initiated the Ciclesonide/Formoterol Combination Ultrahaler(DPI) Phase 2 studies.

International Clinical Research Director for Ciclesonide (Alvescorn) MDI and Ciclesonide/Formoterol Combination Ultrahaler (DPI) Projects. Responsible for the clinical leadership, management, oversight, execution and accountability of large, global and complex Clinical Development Plan for Ciclesonide and Combination Project. Led labeling negotiations with FDA to obtain approval of Ciclesonide on Jan 10, 2008. The development process and plan included collaboration with Altana/Nycomed Pharma and alignment on overall strategy, target product profile and labeling resulting in a robust clinical program.

Transitioned Alvesco™ and Combination Project from Aventis to Sanofi Aventis. Presented portfolio to head of R&D committee (CODD). Represented clinical development at the Joint Operating Committee (JOC) with Altana/Nycomed to strategize and resolve project related issues. Provided regular updates on strategy, clinical trial results and operational issues related to AlvescoTM and the Combination to CODD.

Led the Global Clinical Sub-Team, ensuring alignment on development plans and timely execution of clinical studies for Alvescont and the Combination Programs. All studies were enrolled ahead of schedule and were executed successfully with positive results. The complete response to FDA's Approvable Letter for the NOA was filed in July 2007. Represented Clinical Investigations as a focal point for global coordination of clinical trials management within the Global Project Team.

Collaborated with Marketing, Health Economics and Medical Affairs on Phase IV Studies to optimize life cycle management. Published the key registration studies in peer reviewed journals and presented numerous abstracts and gave oral presentations of registration studies at AAAAI, ACAAI, ATS, ACCP, AAP etc.

Presented clinical data to the CAG (Core Advisory Group), the National Asthma and Allergy Advisory Boards, the German Pulmonology Advisory Board and the Ciclesonide International Advisory Boards, comprising of KOLs and other thought leaders in asthma and COPD. Complimented on the outcome of results from the efficacy and safety studies.

Recognized as Clinical Development Core Manager in the R&D organization. Only Clinical Director in R&D to be invited two consecutive years to present clinical data at global Forum Research Meetings, organized by the head of R&D to exchange scientific information with the company's top 200 R&D managers.

Aventis Pharmaceuticals, Bridgewater, NJ

December 1999- December 2004 — Senior Distinguished Scientist, Pulmonary Therapeutic Area
Senior Director; Respiratory Medicine

KEY ACHIEVEMENTS

Alvesco MDI NDA filed with FDA on December 23, 2003.

Approvable letter for Alvesco™ received from FDA on Oct 21, 2004.

Nasacort HFA NDA approved, April 15, 2004.

Initiated and effectively led a rapid action core dossier and clinical development team in the strategic planning, aggressive and accelerated timeline management, quality control and establishment of clinical profile for Alvesco™. This included compilation of 15 US pivotal reports with 3 summary documents, integration of Altana phase 1 to 3 safety database with over 8000 patients, competitive labeling, successful filing of the largest eNDA (electronic submission) filed with the Pulmonary Division (14.8 gigabytes, 63 studies in Phase1 to 3 done worldwide) and the first combined pediatric and adult submission filed under ICH guidelines as a Common Technical Document.

Led the Global Clinical Sub-Team in the execution and completion of an accelerated adult and pediatric clinical development program for US registration in the history of global pulmonary clinical development. The combined adult and pediatric submission included over 4000 randomized adults, adolescents and children (down to 4 years of age) with persistent asthma who completed the program in less than 2 years.

Led the Global Clinical Sub-Team in writing and publishing 12 high quality clinical protocols and study reports. Wrote key clinical documents (ISE, ISS and Clinical Overview) ensuring adequate scientific input and review/approval by appropriate experts and committees.

Managed and maintained strongly integrated clinical team development with partner (Altana). Managed the publishing of thorough and well-written quality documents, with strict adherence to SOPS and Aventis standards. Filed the 120-day safety update on schedule.

Managed FDA establishment inspection for Alvesco™. Led Aventis team in executing strategy for FDA inspection including 6 mos of preparations, managing resources, establishing a "rapid response team" across Aventis, Altana and vendors associated with the Alvesco MDI Project. No major issues dentified and no 483 was issued. Complimented by senior management on flawless execution.

Supervised, reviewed and contributed towards the preparation of the FDA Briefing Document for the lens opacity findings. Organized and chaired an expert ophthalmology panel to interpret data. Constituted an IDMC and conducted a global state of the art ophthalmological study, the results of which (no lens opacity) were convincing to health authorities to enable Alvesco™ to achieve class labeling. Designed and executed the first ever growth study done under FDA guidelines. Alvesco™ was shown to not have any growth effects unlike other inhaled corticosteroids.

Provided medical guidance for the approval of Nasacort HFA. Collaborated with regulatory affairs to rewrite package insert and revise clinical section resulting in FDA approval.

Submitted Pre-IND and IND packages for the Cic/FF Combination project to FDA. As co-chair of the Joint Clinical Sub-Team for the Combination project and in close consultation with development partner Altana, developed the clinical strategy, and development plan and led the team in productive discussions with FDA. Supervised, reviewed and contributed towards the preparation of the FDA Pre-IND Briefing Document and the IND. Organized and chaired the first Joint Clinical Development meeting in NYC with alliance partner Altana.

Fully participated in the evolution of the multidose dry powder inhaler called Ultrahaler---a state of the art device, working in close collaboration with our CMC and IA colleagues in the UK. Conducted several positive studies with the Ultrahaler.

Presented key results and of the Alvesco™ development program to international and national asthma experts at Core Advisory Board Meetings, US National Allergy/Asthma Meetings and European International Advisory Board Meetings. Received positive feedback and complimented on the success of the program in reference to the quality, content and key messages of the results.

Rhone Poulenc Rorer Pharmaceuticals, Collegeville, PA

June 1996- November 1999 — Director, Global Clinical Research, Respiratory Medicine, Research and DevelopmentGlobal Clinical Project Leader, Corticosteroids, Global Clinical Director, Alvesco & Cic/FF Combination Project

Responsible for worldwide development of orally inhaled corticosteroids, cromones and intranasal corticosteroids for asthma and allergic rhinitis.

Responsibilities included the establishment and execution of the global strategy for the development of these compounds and ensuring that the strategy was consistent with corporate objectives.

Collaborated with Corporate Strategic Marketing, Regulatory Affairs and Discovery colleagues to ensure development of potential new products, line extensions, and in-license compounds.

KEY ACHIEVEMENTS

NDA/MAA Submissions	Year	Status
Nasacort HFA 134a NDA (AdulUPeds)	Dec. 1996	Approved
Nasacort AQ (Ped.) sNDA	Dec. 1996	Approved
Nasacort AQ MAA (Adult/Peds)	Feb. 1997	Approved
Azmacort HFA NOA (Adult/Peds.)	Mar. 1997	Approved
Azmacort HFA MAA--EU (AdulUPeds.)	Dec. 1998	Approved
Azmacort HFA NOA (Canada)	Sept 1998	Approved
Azmacort HFA NOA (Australia)	June 1998	Approved
Azmacort HFA QD NOA	July 1999	Approved
Intal HFA MAA (AdulUPeds.)	Dec. 1997	Approved
Intal HFA MAA (Australia)	April 1998	Approved
Tilade HFA MAA (AdulUPeds)	Dec. 1997	Approved

Provided medical review and leadership of key dossier documents -for NDAs, MAAs, INDs, CTXs and expert reports. Authored briefing documents and responses to clinical issues for regulatory authorities globally. Key participant in driving the clinical strategy with respect to CDPs, expert reports etc. Represented RPR Clinical Development at regulatory agencies worldwide and made presentations on several occasions.

Provided clinical strategy, guidance and leadership during discussions and due diligence meetings with Altana Pharma for co-development of Ciclesonide which resulted in a more strategic and focused development program. Led the RPR team at the FDA EOP 2 meeting to discuss clinical development plans for Phase 3.

Provided clinical strategy, guidance and leadership for the Corticosteroid Team and Azmacort / Nasacort project teams. Co-chaired RPR 106541 (inhaled soft steroid) team. Represented project team at DCC, expert meetings and developed the clinical strategy with regulatory and marketing colleagues.

Managed Azmacort HFA and Nasacort HFA and AQ programs on a global basis. Organized and managed clinical documents and study reports for U.S. NDA (Azmacort) for both BID and QD dosing.

Managed Tilade HFA and Intal HFA regulatory submissions and obtained approval in key countries. Initiated the Phase 2B program of RPR 106541 (soft steroid) in U.S., Japan and completed study ahead of schedule despite patient enrollment difficulties. Presented updates at portfolio meeting to CEO and senior management. Project was discontinued for safety reasons.

Team Leader for joint FDA Pulmonary/ Endocrinology Growth Advisory Meeting in July 1998 resulting in favorable outcome for RPR. Received cash award from RPR senior management as recognition.

Presented abstracts on Azmacort HFA and Nasacort AQ at international meetings such as AAAAI, ERS, ATS and World Asthma Congress between October 1996 and November 1999. Five manuscripts on Azmacort HFA and one on Nasacort AQ were published in peer reviewed journals. Collectively, the aggressive efforts to enhance the image of Azmacort HFA and Nasacort AQ globally, in time for launch was appreciated by Marketing colleagues, worldwide.

Presented a series of Azmacort HFA clinical presentations (lectures) to chest physicians, allergists, pulmonologists, general practitioners and opinion leaders from France, U.K., U.S., Germany, Turkey, Norway, Italy, Spain, Israel, Ireland, South Africa and Poland.

Supervised a staff of 13 people (2 MDs, 5 PhD's) at both US and France Corporate Headquarters.

Astra Pharmaceuticals, Westborough, MA

November 1988- June1996 Director, Respiratory Clinical Development

Responsible for establishing the department of Respiratory Clinical Development (phase 2 to 4) for a new prescription medicine division (Rx Division) to perform clinical development of respiratory/allergy products, strategic planning, establish clinical profile, and assemble documentation for INDs and NDAs and obtain regulatory approval for products, coming from Astra Research and Development in Sweden.

Provided expertise, guidance and strategic planning for competitive clinical development of R&D compounds in respiratory/allergy in Phase 2 to 4.

Responsible for submitting IND for Pulmicort Turbuhaler, strategic planning for U.S. clinical development program and conducting clinical studies (done ahead of schedule) which included the analysis and compilation of data, assembly and submission of NDA to the Pulmonary Division.

Served as clinical project leader and medical expert for all U.S. respiratory/allergy clinical programs (i.e., Pulmicort Turbuhaler, Formoterol Turbuhaler, Albuterol Turbuhaler, Rhinocort MDI, RhinocortTurbuhaler, Rhinocort Aqua and insured the provision of medical overview with continuous monitoring of safety for all products.

Together with Marketing and Sales, established comprehensive market analysis and market potential product positioning and launch platform for the marketing of respiratory/allergy prescription medicines coming from the parent company, Astra AB in Sweden.

Served as international liaison with different project groups within corporate research group at Astra AB, Sweden and provided expertise to integrate European/U.S. clinical projects with the goal of submitting integrated clinical efficacy and safety data in the U.S.

Played key role in clinical development and approval of Rhinocort MDI, including negotiations with Pilot Division (CDER). Served on committee to respond to FDA's labeling changes (NDA Day).

Provided medical and scientific advice to Astra Business Development Unit (US) for assessing strategic opportunities and other forms of collaboration.

In collaboration with Finance and Project Tracking, developed systems to monitor clinical programs and assured that target dates to regulatory, biostatistics and marketing were met.

Provided medical support to Regulatory Affairs for INDs and NDAs, product labeling, and information to health care professionals and patients.

Coordinated with Departments of Regulatory Affairs and Drug Safety to ensure that product information presented to the FDA and other public/scientific/health care professions and patients were accurate and met ethical standards.

Prepared and presented position papers, product development plans and strategic business plans for senior management to achieve results consistent with corporate goals.Participated in workshop with worldwide opinion leaders on steroids and asthma which resulted in proceedings published as a supplement in Respiratory and Critical Care Journal.

Key participant in development of divisional standard operating procedures resulting in corporate fulfillment of ethical and professional standards.

Established Astra Respiratory Advisory Board to collaborate and consult with academic consultants on novel ideas for prospective research.

Supervised a staff of 8 personnel (2MDs, 2 PhDs)

Membership in Professional Societies:

American Academy of Allergy Asthma and Immunology
Joint Council of Allergy Asthma and Immunology
Drug Information Association
American Thoracic Society
American College of Allergy Asthma and Immunology
American College of Chest Physicians
European Respiratory Society

Education:

Armed Forces Medical College University of Poona, India	MD
University of Poona, Poona, India	BS

Post Graduate Medical Education:

Faculty, Div Int Medicine, USF, Tampa, USA

Senior Resident, Registrar
Darlington & Middlesborough General Hospitals,
Middlesborough, UK

Sr Resident, Watford General & Charing Cross Hospitals, UK

Resident, St. Albans & Barnett General Hospitals, UK

Medical Intern, University of Calcutta
Affiliated Hospitals, Calcutta, India

Publications and Abstracts:

Authored over 75 primary manuscripts and published and presented over 400 abstracts at major respiratory meetings. List provided upon request.