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Novel Drugs and Biologics of 2016: A Boom for Neurodrugs in the Pipeline

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ABSTRACT

This article provides a brief overview of novel drugs approved by the U.S. FDA in 2016. It also focuses on the emerging boom in the development of neurodrugs for central nervous system (CNS) disorders. These new drugs are innovative products that often help advance clinical care worldwide, and in 2016, twenty-two such drugs were approved by the FDA. The list includes the first new drug for disorders such as spinal muscular atrophy, Duchenne muscular dystrophy or hallucinations and delusions of Parkinson's disease, among several others. Notably, nine of twenty-two (40%) were novel CNS drugs, indicating the industry shifting to neurodrugs. Neurodrugs are the top selling pharmaceuticals worldwide, especially in America and Europe. Therapeutic neurodrugs have proven their significance many times in the past few decades, and the CNS drug portfolio represents some of the most valuable agents in the current pipeline. Many neuroproducts are vital or essential medicines in the current therapeutic armamentarium, including dozens of "blockbuster drugs" (drugs with $1 billion sales potential). These drugs include antidepressants, antimigraine medications, and anti-epilepsy medications. The rise in neurodrugs' sales is predominantly due to increased diagnoses of CNS conditions. The boom for neuromedicines is evident from the recent rise in investment, production, and introduction of new CNS drugs. There are many promising neurodrugs still in the pipeline, which are developed based on the validated "mechanism-based" strategy. Overall, disease-modifying neurodrugs that can prevent or cure serious diseases, such as multiple sclerosis, epilepsy, and Alzheimer's disease, are in high demand.

KEYWORDS: Novel drugs; NCEs, First-in-class; CNS drugs; Blockbuster drugs; Neurodrugs.

Introduction

The U.S. FDA is the leading authority for drug approvals worldwide, and each year, the FDA approves a variety of new drugs and biological products. Figure 1 shows the number of novel drugs approved by the FDA during the past 10 years (Reddy, 2012, 2013, 2014; Reddy and Reddy, 2016). Some of these pharmaceuticals are innovative or novel products that have never been used by patients, whereas other products are somewhat related to previously approved products with major improvements in the delivery or its method of treating a medical condition. New drugs which have not been approved by the FDA previously are classified as new molecular entities ("NMEs"). A new chemical entity (NCE) is a drug that contains no active moiety that has been approved by the FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

The landscape of big pharmaceutical companies is swiftly adapting to the changes in the global economy, legislation by governing agencies, and the needs of patients (Reddy, 2015). The Hatch-Waxman Act of 1984 transformed the pharmaceutical business with respect to generic drugs. Today, big companies drive innovation by introducing new drugs despite tremendous risks and regulatory hurdles. Drug development is a lengthy and expensive process, estimated to cost $1.2 billion ("high risk – high reward" business), and 5 to 10 years of time to introduce a new drug to the market (Reddy and Woodward, 2004; Scannel et al., 2012; Reddy, 2012; 2013; 2014). Despite steady increases in R&D development, the number of new drugs approved has greatly decreased during the past decade (Scannel et al., 2012). The pipeline of new drugs is still strong and growing, but there is still a pipeline syndrome for blockbuster drugs (drugs with $1 billion sales potential). Consequently, the pharmaceutical industry continues to adapt a dynamic model for new drugs in the developmental pipelines. There are many regulatory pathways or schemes for accelerated approval of novel drugs (Table 2).

New drug approvals are considered an index of industry innovation and return on R & D investments. Despite the accelerated approval processes of the FDA, the 2016 approval rate is drastically low compared to the previous few years (Fig. 1). From 2007 through 2015, FDA approvals averaged about 30 new drugs per year. As shown in Table 1, the novel drugs approved in 2016

were either approved as new molecular entities (NMEs) under New Drug Applications (NDAs), or as new therapeutic biologics under Biologics License Applications (BLAs). According to the FDA, novel drugs are innovative products that serve previously unmet medical needs or otherwise significantly help advance patient care and public health. NMEs have chemical structures that have never received FDA approval; however, in most cases, an NME may have actions similar to earlier drugs and may not necessarily offer unique clinical advantages over existing therapies. The new drugs approved in 2016 included treatments for spinal muscular atrophy, Duchenne muscular dystrophy, hallucinations and delusions of Parkinson's disease, primary biliary cirrhosis, and hepatitis C, ovarian cancer, bladder cancer, soft tissue sarcoma, and chronic lymphocytic leukemia. Most of these drugs are notable for their potential therapeutic impact and unique contributions to health care that would lead to improvements in public health. This article provides an overview of the new drugs approved in 2016, highlighting the boom in the development of neurodrugs for central nervous system (CNS) disorders.

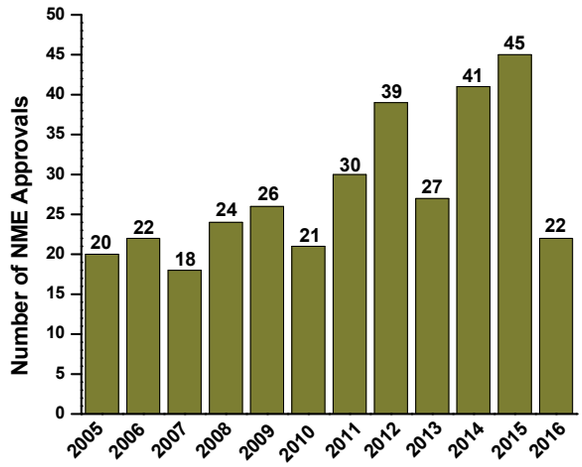

Fig. 1. New drug approvals from 2005 to 2016 in the United States. *Source: FDA*

TABLE 1

Novel new drug approvals in 2016 (alphabetical order).

Brand Drug	*Common name (API)*	*Approval Date*	*Indications*
Spinraza	Nusinersen	12/23/2016	To treat children and adults with spinal muscular atrophy
Rubraca	Rucaparib	12/19/2016	To treat women with a certain type of ovarian cancer
Eucrisa	crisaborole	12/14/2016	To treat mild to moderate eczema (atopic dermatitis) in patients two years of age and older
Zinplava	bezlotoxumab	10/21/2016	To reduce the recurrence of Clostridium difficile infection in patients aged 18 years or older
Lartruvo	olaratumab	10/19/2016	To treat adults with certain types of soft tissue sarcoma
Exondys 51	Eteplirsen	9/19/2016	To treat patients with Duchenne muscular dystrophy
Adlyxin	lixisenatide	7/27/2016	To improve glycemic control (blood sugar levels)
Xiidra	lifitegrast ophthalmic solution	7/11/2016	To treat the signs and symptoms of dry eye disease
Epclusa	sofosbuvir and velpatasvir	6/28/2016	To treat all six major forms of hepatitis C virus
NETSPOT	gallium Ga 68 dotatate	6/1/2016	A diagnostic imaging agent to detect rare neuroendocrine tumors
Axumin	fluciclovine F 18	5/27/2016	A new diagnostic imaging agent to detect recurrent prostate cancer
Ocaliva	obeticholic acid	5/27/2016	To treat rare, chronic liver disease
Zinbryta	daclizumab	5/27/2016	To treat multiple sclerosis
Tecentriq	atezolizumab	5/18/2016	To treat urothelial carcinoma, the most common type of bladder cancer
Nuplazid	pimavanserin	4/29/2016	To treat hallucinations and delusions associated with psychosis experienced by some people with Parkinson's disease
Venclexta	venetoclax	4/11/2016	For chronic lymphocytic leukemia in patients with a specific chromosomal abnormality
Defitelio	defibrotide sodium	3/30/2016	To treat adults and children who develop hepatic veno-occlusive disease with additional kidney or lung abnormalities after they receive a stem cell transplant from blood or bone marrow called hematopoietic stem cell transplantation
Cinqair	reslizumab	3/23/2016	To treat severe asthma
Taltz	ixekizumab	3/22/2016	To treat adults with moderate-to-severe plaque psoriasis.
Anthim	obiltoxaximab	3/18/2016	To treat inhalational anthrax in combination with appropriate antibacterial drugs.
Briviact	brivaracetam	2/18/2016	To treat partial onset seizures in patients age 16 years and older with epilepsy.
Zepatier	elbasvir and grazoprevir	1/28/2016	To treat patients with chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adult patients.

Source: 2016 Novel drugs summary, FDA January 2017.

Prominent Novel Drugs of 2016

In 2016, the FDA approved 22 novel drugs for clinical use. The list includes 9 new drugs (41%) to treat rare or "orphan" diseases that affect 200,000 or fewer Americans (Table 1). This is significant because patients with rare diseases often have few, if any, drugs available to treat their conditions (Reddy, 2012, 2013, 2014). The major examples of drugs that treat rare diseases among the 2016 novel drugs include Exondys (Duchenne muscular dystrophy) and Spinraza (spinal muscular atrophy). In 2016, the FDA categorized 8 of the 22 (36%) approved drugs as First-in-Class, which is an indicator of the innovative nature of a drug (Table 1). Such drugs often have mechanisms of action distinct from those of previous or existing drugs. The noteworthy first-in-class products include Defitelio, approved for treating hepatic veno-occlusive disease in patients with additional kidney or lung abnormalities after receiving hematopoietic stem cell transplantation – a stem cell transplant from blood or bone marrow –, and Zinbryta, which is approved to treat multiple sclerosis (CNS condition).

The FDA uses a number of regulatory tracks to expedite the development and approval of novel drugs, including Fast Track, Breakthrough, Priority Review, and Accelerated Approval. Fast Track drugs have the potential to address unmet medical needs. Eight of the 22 novel drugs (36%) were categorized as Fast Track, including Anthim, Defitelio, Epclusa, Exondys, Lartruvo, Ocaliva, Spinraza, Zinplava (Table 1). Breakthrough therapies are drugs that are a major improvement over other available therapies and this track is designed to help shorten the development time of the new therapy. The FDA designated 7 of 22 (32%) drugs as Breakthrough therapies, including Epclusa, Lartruvo, Nuplazid, Rubraca, Tecentriq, Venclexta, Zepatier (Table 1). A drug receives a Priority Review if the FDA determines that the drug could provide a significant advance in medical care, expediting the approval process to six months instead of the standard 10 months. Fifteen of the 22 (68%) novel drugs were designated Priority Review, including Axumin, Defitelio, Epclusa, Exondys 51, Lartruvo, Netspot, Nuplazid, Ocaliva, Rubraca, Spinraza, Tecentriq, Venclexta, Xiidra, Zepatier, Zinplava (Table 1). The Accelerated Approval track allows for faster approval of a drug that treats serious or life threatening illnesses. Six of the 22 new drugs (27%) were approved under the Accelerated Approval program, including Exondys, Lartruvo, Ocaliva, Rubraca, Tecentriq, Venclexta (Table 1). Such approvals often rely on a "surrogate endpoint" (biochemical or clinical outcomes) that predict a clinical response of the drug.

Emerging Boom for Neurodrugs in the Pipeline

There is resurgence in the development of neurodrugs for CNS disorders (see Table 2). Neurodrugs are the top selling pharmaceuticals worldwide, especially in America and Europe. Therapeutic neurodrugs have proven their mettle many times in the past few decades, and ten of the twenty-five best-selling drugs from 2016 were neurodrugs. Furthermore, some of the most valuable agents in the current pipeline are CNS drugs. Many neuroproducts are vital or essential medicines in the current therapeutic armamentarium, including dozens of "blockbuster drugs" (drugs with $1 billion sales potential). For example, Prozac (fluoxetine) has revolutionized the antidepressant market. The antimigraine Imitrex (sumatriptan) has opened new frontiers in treating migraine headaches; Keppra (levetiracetam) proved valuable for treating intractable epilepsy. Other examples include anti-psychotic drug Abilify (aripiprazole), bipolar and schizophrenia treatment Zyprexa (olanzapine), Alzheimer's treatment Aricept (donepezil), and the Multiple Sclerosis drug Copaxone (glatiramer acetate). The list of CNS blockbusters includes many biologicals & biosimilars, such as Tysabri (natalizumab). America remains the world's biggest consumer of CNS drugs but there is rise of CNS drug use in Europe and Asian continents. The US pharmaceutical companies witnessed a big boom in CNS drug consumption in the last year with an excess of $100 billion in sales. The top CNS pharmaceutical companies include Pfizer, Biogen Idec, Novartis, Otsuka, Teva, J &J, Lilly, Merck, AstraZeneca, Shire, UCB, Lundbeck, Eisai, GSK and Sanofi. Pfizer's number one spot is predominately from the blockbuster sales of its pain drug, Lyrica (pregabalin), among other top selling neurodrugs. The rise in neurodrugs' sales is predominately due to improved diagnoses of CNS conditions. While branded drugs account for over 50% of revenue for the top CNS companies, generics play an important role in the CNS drug market. There was a transient, bleak forecast with exit of companies, including GSK, BMS, and AstraZeneca, from CNS field. However, in 2017, the FDA approved five new CNS drugs highlighting a resurging boom in the demand for medicines for brain disorders. The drug approval trends clearly reveal the industry shifting to niche or orphan diseases. There are many promising neurodrugs still in the pipeline, which are developed based on "mechanism-based" strategy. Apart from preclinical trials, *in vitro* and *in silico* models are invaluable for accelerated development of CNS products, resulting in successful screening through the FDA's stringent guidelines for efficacy and safety, especially regarding potential side effects of neurodrugs.

TABLE 2

Pharmacological list of new drugs of 2016.

Cardiology/Vascular Diseases
Byvalson (nebivolol and valsartan); Allergan; For the treatment of hypertension.
Yosprala (aspirin and omeprazole); Aralez Pharmaceuticals; For the prevention of cardiovascular and cerebrovascular events.
Dermatology
Ameluz (aminolevulinic acid hydrochloride); Biofrontera Pharma; For the treatment of actinic keratosis.
Eucrisa (crisaborole) ointment; Pfizer; For the treatment of atopic dermatitis.
Taltz (ixekizumab); Eli Lilly; For the treatment of plaque psoriasis.

TABLE 2 *Contd…*

Endocrinology
Adlyxin (lixisenatide); Sanofi Aventis; For the treatment of type II diabetes.
Soliqua 100/33 (insulin glargine and lixisenatide injection); Sanofi Aventis; For the treatment of inadequately controlled type II diabetes.
Xultophy 100/3.6 (insulin degludec and liraglutide injection); Novo Nordisk; For the treatment of inadequately controlled type II diabetes.
Family Medicine
Byvalson (nebivolol and valsartan); Allergan; For the treatment of hypertension.
Onzetra Xsail (sumatriptan nasal powder); Avanir; For the treatment of migraine.
Soliqua 100/33 (insulin glargine and lixisenatide injection); Sanofi Aventis; For the treatment of inadequately controlled type II diabetes.
Xultophy 100/3.6 (insulin degludec and liraglutide injection); Novo Nordisk; For the treatment of inadequately controlled type II diabetes.
Gastroenterology
Zinplava (bezlotoxumab); Merck; For the treatment of recurrent Clostridium difficile infection in patients receiving antibacterial treatment.
Genetic Disease
Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy.
Hematology
Afstyla (Antihemophilic Factor (Recombinant), Single Chain); CSL Behring; For the treatment of hemophilia A.
Idelvion (Coagulation Factor IX (Recombinant), Albumin Fusion Protein); CSL Behring; For the treatment of hemophilia B.
Kovaltry [Antihemophilic Factor (Recombinant)]; Bayer ; For the treatment of hemophilia A.
Opdivo (nivolumab); Bristol-Myers Squibb; For the treatment of classical Hodgkin lymphoma.
Venclexta (venetoclax); AbbVie; For the treatment of chronic lymphocytic leukemia with 17p deletion.
Hepatology (Liver, Pancreatic, Gall Bladder)
Defitelio (defibrotide sodium); Jazz Pharmaceuticals; For the treatment of hepatic veno-occlusive disease with renal or pulmonary dysfunction following HSCT.
Ocaliva (obeticholic acid); Intercept Pharmaceuticals; For the treatment of primary biliary cholangitis.
Vemlidy (tenofovir alafenamide); Gilead Sciences; For the treatment of chronic hepatitis B.
Zepatier (elbasvir and grazoprevir); Merck; For the treatment of chronic HCV genotypes 1 or 4.
Immunology
Afstyla (Antihemophilic Factor (Recombinant), Single Chain); CSL Behring; For the treatment of hemophillia A.
Descovy (emtricitabine and tenofovir alafenamide); Gilead; For the treatment of HIV-1 infection.
Epclusa (sofosbuvir and velpatasvir) ; Gilead Sciences; For the treatment of hepatitis C.
Odefsey (emtricitabine, rilpivirine, and tenofovir alafenamide); Gilead Sciences; For the treatment of HIV-1 as initial therapy.
Taltz (ixekizumab); Eli Lilly; For the treatment of plaque psoriasis.
Vaxchora (Cholera Vaccine, Live, Oral); PaxVax; For active immunization against Cholera.
Infections and Infectious Diseases
Anthim (obiltoxaximab); Elusys Therapeutics; For the treatment of inhalational anthrax.
Descovy (emtricitabine and tenofovir alafenamide); Gilead; For the treatment of HIV-1 infection.
Epclusa (sofosbuvir and velpatasvir) ; Gilead Sciences; For the treatment of hepatitis C, Approved June 2016
Odefsey (emtricitabine, rilpivirine, and tenofovir alafenamide); Gilead Sciences; For the treatment of HIV-1 as initial therapy.
Syndros (dronabinol oral solution); Insys Therapeutics; For the treatment of anorexia associated with AIDS and nausea and vomiting associated with cancer chemotherapy.
Vaxchora (Cholera Vaccine, Live, Oral); PaxVax; For active immunization against Cholera.
Vemlidy (tenofovir alafenamide); Gilead Sciences; For the treatment of chronic hepatitis B.
Zepatier (elbasvir and grazoprevir); Merck; For the treatment of chronic HCV genotypes 1 or 4.
Zinplava (bezlotoxumab); Merck; For the treatment of recurrent Clostridium difficile infection in patients receiving antibacterial treatment.
Musculoskeletal
Exondys 51 (eteplirsen); Sarepta Therapeutics; For the treatment of Duchenne muscular dystrophy with mutated DMD gene amenable to exon 51 skipping.
Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy.
Zinbryta (daclizumab) ; Biogen; For the treatment of relapsing multiple sclerosis.
Nephrology
Cabometyx (cabozantinib); Exelixis; For the treatment of advanced renal cell carcinoma.
Lenvima (lenvatinib); Eisai; For the treatment of advanced renal cell carcinoma.
Rayaldee (calcifediol); Opko Health; For the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease.
Neurology (CNS products)
Briviact (brivaracetam); UCB; For the treatment of partial onset seizures related to epilepsy.
Carnexiv (carbamazepine); Lundbeck; replacement therapy when oral administration is not feasible, in adults with seizures.
Exondys 51 (eteplirsen); Sarepta Therapeutics; For the treatment of Duchenne muscular dystrophy with mutated DMD gene amenable to exon 51 skipping.
Nuplazid (pimavanserin); Acadia Pharmaceuticals; For the treatment of hallucinations and delusions associated with Parkinson's disease.
Nuplazid (pimavanserin); Acadia Pharmaceuticals; For the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
Onzetra Xsail (sumatriptan nasal powder); Avanir; For the treatment of migraine.
Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy.
Troxyca ER (oxycodone + naltrexone); Pfizer; For the management of severe pain.
Zinbryta (daclizumab); Biogen; For the treatment of relapsing multiple sclerosis.
Obstetrics/Gynecology (Women's Health)
Intrarosa (prasterone vaginal insert); Endoceutics; For the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.
Rubraca (rucaparib); Clovis Oncology; For the treatment of advanced ovarian cancer in women with deleterious germline or somatic BRCA mutation.
Oncology
Cabometyx (cabozantinib); Exelixis; For the treatment of advanced renal cell carcinoma.
Keytruda (pembrolizumab); Merck; For the treatment of head and neck squamous cell cancer.

TABLE 2 *Contd…*

Oncology
Lartruvo (olaratumab); Eli Lilly; For the treatment of soft tissue sarcoma.
Lenvima (lenvatinib); Eisai; For the treatment of advanced renal cell carcinoma.
Opdivo (nivolumab); Bristol-Myers Squibb; For the treatment of classical Hodgkin lymphoma.
Opdivo (nivolumab); Bristol-Myers Squibb; For the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck.
Rubraca (rucaparib); Clovis Oncology; For the treatment of advanced ovarian cancer in women with deleterious germline or somatic BRCA mutation.
Sustol (granisetron); Heron Therapeutics; For the prevention of chemotherapy-induced nausea and vomiting.
Syndros (dronabinol oral solution); Insys Therapeutics; For the treatment of anorexia associated with AIDS and nausea and vomiting associated with cancer chemotherapy.
Tecentriq (atezolizumab); Genentech; For the treatment of urothelial carcinoma and metastatic non-small cell lung cancer.
Venclexta (venetoclax); AbbVie; For the treatment of chronic lymphocytic leukemia with 17p deletion.
Ophthalmology
Humira (adalimumab); Abbvie; For the treatment of uveitis.
Xiidra (lifitegrast); Shire; For the treatment of dry eye disease.
Pediatrics/Neonatology
Exondys 51 (eteplirsen); Sarepta Therapeutics; For the treatment of Duchenne muscular dystrophy with mutated DMD gene amenable to exon 51 skipping.
Kovaltry [Antihemophilic Factor (Recombinant)]; Bayer ; For the treatment of hemophillia A.
Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy
Pulmonary/Respiratory Diseases
Bevespi Aerosphere (glycopyrrolate and formoterol fumarate); AstraZeneca; For the treatment of chronic obstructive pulmonary disease.
Cinqair (reslizumab); Teva Pharmaceuticals; For the treatment of severe asthma.
Tecentriq (atezolizumab); Genentech; For the treatment of urothelial carcinoma and metastatic non-small cell lung cancer.
Urology
Tecentriq (atezolizumab); Genentech; For the treatment of urothelial carcinoma and metastatic non-small cell lung cancer.
Vaccines
Vaxchora (Cholera Vaccine, Live, Oral); PaxVax; For active immunization against Cholera.

Source: 2016 Novel drugs summary, FDA January 2017.

Conclusions

In 2016, a drastically low 22 novel drugs were approved by the FDA, unlike in years past. From 2007 through 2015, FDA approvals averaged about 30 new drugs per year. As shown in Table 1, the FDA approved 22 novel drugs either as NMEs or BLAs. Most of these drugs addressed needs of uncommon diseases with few treatment options. A significant 9 of the 22 novel drugs were CNS pharmaceuticals approved for treating a variety of brain diseases, resulting in a record growth for the field of CNS pharmaceuticals. The rise in neurodrug sales is mainly attributed to a higher aging population with one or more of the CNS conditions discussed in this article. Despite such growing trends and a strong pipeline, there is still a big gap in medical treatment for many brain disorders. Continued investment into CNS pharmaceutical development will be necessary for continued success of CNS therapies with regards to gaining FDA approval, and consequently, clinical application to benefit patient lives.

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Brief Biosketch of Prof. Samba Reddy (USA)

Prof. Samba Reddy

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Prof. Samba Reddy is a Professor & NIH Counteract Investigator at the College of Medicine at Texas A&M University-- a premier institution in America and the largest university in Texas. He is a highly trained pharmacist-pharmacologist developing new therapeutics for epilepsy and chemical neurotoxicity. His lab has been conducting pioneering investigations on neurosteroid interactions at synaptic and extrasynaptic GABA-A receptors. His research has been continuously funded by the NIH for over 12 years. He is the principal investigator of an NIH Cooperative Agreement U01 project focusing on novel treatments for organophosphate and chemical nerve agent intoxication. He directs a DOD project on post-traumatic epilepsy after traumatic brain injury. He teaches both medical & graduate level courses and directs a research team in CNS drug development. Prof. Reddy is has made exceptional contributions to the pharmaceutical field through his services during the past 20 years, in addition to serving as an expert member in federal government panels in Washington D.C.

Prof. Reddy got his Pharmacy degree at Kakatiya University in Warangal, in 1992 and his Ph.D. at the Panjab University in Chandigarh, India, in 1998. He worked as postdoctoral fellow at the U.S. National Institutes of Health in the intramural NINDS, Bethesda, Maryland. In 2008 he joined the faculty of the Texas A&M University College of Medicine in Bryan, Texas, where he has been teaching and conducting NIH-funded research on epilepsy neuroscience and drug development. Previously, he also done research at the North Carolina State University. He has published 170 papers (h-index 40), co-authored 300 presentations, and delivered 130 lectures worldwide.

He is the Editor-in-Chief of *International Journal of Pharmaceutical Sciences and Nanotechnology*, an Editor of *Epilepsy Currents,* and a Review Editor for *Frontiers in Neuroscience*, and *Frontiers in Pharmacology journals.* He serves as expert member/adviser in federal scientific committees, including the National Institutes of Health (NIH), U.S.DOD, U.S.EPA and U.S. Pharmacopoeia (USP), the gold-standard compendium of pharmaceuticals. He won a number of awards for his research excellence, including the NIH FARE Award (2000), ASPET Award (2004), Sigma-Xi Research Award (2006), ASIOA Award (2007), NATA Research Award (2012), TANA Award (2013), ATA Science Award (2014), and Texas A & M Medical Research Excellence Award (2015). He was elected fellow of both the *American Association of Pharmaceutical Scientists* (AAPS) and the *American Association for the Advancement of Science* (AAAS), which is the world's largest scientific society and publisher of the journal Science. In 2016, Prof. Reddy has been inducted as *Fellow of American Epilepsy Society (AES)* for his professional accomplishments and contributions to epilepsy research. In 2014, Prof. Reddy has deservingly earned the title "**Hind Rattan**" (Jewel of India) for his valuable scientific contributions and services. Prof. Reddy has been nominated for the India's coveted civilian award "**Padma Shri**". He is a highly aspiring candidate from India to win the Nobel Prize through translational pharmaceutical research.