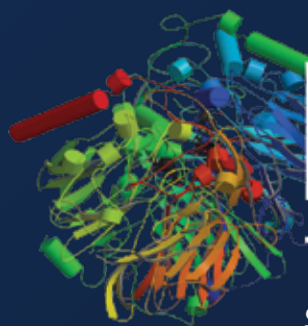




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PEGS is Cambridge Healthtech Institute (CHI)'s flagship biologics meeting, and is widely considered the industry's leading event on protein and antibody engineering. Its successful accolades include an annual attendance of over 1800 participants at the PEGS Summit in Boston, a record attendance of over 500 attendees at PEGS Europe last year, a successful launch of PEGS China in 2014, and now, we proudly announce PEGS Korea.

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Track 1

Protein & Antibody Engineering

Track 2

Next- Generation Antibody Therapeutics

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Keynote Presentations:



At the Crossroads: Getting to Reproducible Research Antibodies

Andrew Bradbury, MBBS, Ph.D., Biosciences Division, Los Alamos National Laboratory



Developing Antibodies against Difficult Targets Using Computational Approaches

Gregory P. Adams, Ph.D., Director, Biological Research and Therapeutics, Fox Chase Cancer Center

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TUESDAY, SEPTEMBER 1, 2015

7:30 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks

Junho Chung, Ph.D., Professor and Chairman, Biochemistry and Molecular Biology, Seoul National University

KEYNOTE PRESENTATIONS

8:40 At the Crossroads: Getting to Reproducible Research Antibodies



Andrew Bradbury, MBBS, Ph.D., Biosciences Division, Los Alamos National Laboratory,

Researchers all over the world routinely use antibodies, a critical class of commercially supplied reagents that are frequently unreliable. This situation affects reproducibility in biomedical research, wastes millions of dollars annually, and may affect clinical trials. This talk will provide an overview of the problem, argue that the time has come to express antibodies recombinantly and refer to them by their sequences, and provide possible ways to get to this ideal.

9:20 Targeted Protein Therapeutics (TPTs) for the Treatment of Cancer



Gregory P. Adams, Ph.D., Chief Development Officer, Viventia Bio

TPTs are fully biologic constructs containing antibody fragments and protein toxin payloads in a single engineered molecule. We have developed fully deimmunized payloads for the treatment of systemic disease and non-deimmunized payloads for use in the treatment of loco regional disease. Results from our phase II clinical trials performed in non-muscle invasive bladder cancer and head and neck cancer will be presented along with preclinical and phase I clinical trial results supporting the deimmunization and function of our deBouganin payload.

10:00 Coffee Break

TARGET DISCOVERY AND VALIDATION

10:30 Identification of New Therapeutic Targets of Hepatocellular Carcinoma



Gwanghee Lee, Ph.D., Cancer Project Leader, Therapeutic Strategic Unit, Asia Pacific R&D, Sanofi

Liver cancer is the second leading cause of cancer death in Korea and worldwide. However, the current treatment option is limited. With the advent of antibody engineering technique and cancer immunotherapy, target identification and validation become more important. To address the unmet medical needs, we have been implementing efforts to identify new therapeutic targets of hepatocellular carcinoma. Rationale, experimental design and preliminary data will be presented.

BIOLOGICS TARGETING INTRACELLULAR PROTEINS

11:00 Delivering Antibodies into the Cell: Towards a New Therapeutic Paradigm?



Stefan Duebel, Ph.D., Professor and Managing Director, Institute of Biochemistry, Biotechnology and Bioinformatics, Technische Universität Braunschweig, Germany

We developed a systematic evaluation strategy and used it to identify the optimal way to deliver active antibodies into a living cell's cytosol. We also generated the world's first ER intrabody induced knockout mouse - offering a new approach for functional genomics, to validate targets, generate more relevant disease models and even try new strategies for therapeutic intervention. These approaches may very much accelerate the so far quite moderate progress in development of strategies targeting intracellular antigens with therapeutic antibodies.

11:30 Cytosol-Penetrating IgG Antibody and Its Application for Targeting Cytosolic Proteins



Yong-Sung Kim, Ph.D., Professor, Department of Molecular Science & Technology, Ajou University, Korea

Full-length IgG antibodies cannot cross cell membranes of living cells; this limits their use for direct targeting of cytosolic proteins. Here, we describe a general strategy for the generation of intact, full-length IgG antibodies, herein called cytotransmabs, which internalize into living cells and localize in the cytosol. Further, we will show that cytotransmab technology has practical applicability for direct targeting of cytosolic proteins.

12:00 pm Innovative Technologies for Advanced Characterization of Protein Aggregates

Stacy Kenyon, Ph.D., Scientist, Bioscience Development Initiative, Malvern Instruments Ltd.

Understanding the process of protein aggregation is a key component of QbD approaches during biopharmaceutical development or deviation resolution of legacy products. Such in-depth understanding cannot be obtained from standard QC-type analytical methods, but relies on the implementation of advanced characterization technologies. As a consequence of these technologies, the biopharmaceutical industry is now offered detailed insights into protein behaviour, allowing evaluation of product stability and process impact.

12:30 Networking Luncheon in the Exhibit Hall with Poster Viewing (Sponsorship Opportunity Available)

ANTIBODY LIBRARY CONSTRUCTION & DESIGN

1:55 Chairperson's Remarks

Yong-Sung Kim, Ph.D., Professor, Department of Molecular Science & Technology, Ajou University, Korea

2:00 Construction and Use of Large Antibody Libraries in Mammalian Cells

John McCafferty, Ph.D., CEO, IONTAS

Construction of libraries of binders displayed on the surface of mammalian cells will allow the screening of millions of clones by flow sorting while providing information on both the level of expression and the extent of binding within individual clones. The main limitation to achieving this has been the inability to construct large libraries containing a single antibody gene/cell. We have solved this problem by directing the integration of antibody genes into a single genomic locus through the use of site-specific nucleases. The presentation will describe construction of libraries of millions of clones and selection of binders including antibodies formatted as IgGs.

2:30 A Novel Approach to Synthetic Antibody Library Design: SCIEN Principle

Hyunbo Shim, Ph.D., Assistant Professor, Department of Bioinspired Science, Ewha Womans University

Most synthetic antibody libraries have sequence diversity generated by random combinatorial process. While capable of generating very large diversity, this inevitably introduces some undesirable and/or unnatural sequences to the library. In this presentation, a library with non-combinatorial CDR diversity based on SCIEN (Synthetic CDRs Inspired by and Emulating Nature) principle is described. The validity of this design approach was tested by panning on antigens, binding and kinetic assays, and next generation sequencing.

3:00 Detection and Correction of Errors and Biases in NGS of Antibody Repertoires Enables Improved Accuracy for Monoclonal Antibody Discovery

Sai Reddy, Ph.D., Assistant Professor, Biomolecular Engineering, Department of Biosystems, ETH Zurich

Next-generation sequencing (NGS) of antibody repertoires offers the promise to aid existing antibody discovery technologies such as hybridoma and phage/yeast display screening. We have developed a highly accurate experimental-bioinformatic pipeline for performing NGS-based analysis of antibody responses that enables detection and correction of systematic errors and biases in sequencing. Our new method thus allows for more accurate and reliable antibody repertoire data, which can be used for monoclonal antibody discovery.

3:30 Using Multiple Antibody Discovery Platforms to Overcome the Challenges in Developing Antibody Drug against Immune Check Point Targets

Jing Li, M.D., Ph.D., MBA, Vice President, Biologics Discovery, WuXi AppTec

The recent approvals of Pembrolizumab and Nivolumab, the two anti PD-1 antibodies, have attracted more attention to the immune check point targets. However the general protein sequence homology of those targets between human and mouse species is low, posing significant challenge on preclinical *in vivo* testing of such antibody drug candidates. We will show how to utilize different antibody discovery platforms to overcome the challenge and to expedite the drug discovery process.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

THERAPEUTIC ENZYME DEVELOPMENT

4:45 Molecular Engineering to Improve the Therapeutic Potential of the Enzyme L-Asparaginase Used for the Treatment of Leukemia

Manfred Konrad, Ph.D., Professor, Research Director, Enzyme Biochemistry, Max Planck Institute for Biophysical Chemistry

The therapeutic effect of the clinically established enzyme drug L-asparaginase

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(LASNase) relies on the fact that cancerous lymphoblasts depend on the supply of free L-asparagine from the blood. FDA-approved LASNases are of bacterial origin, despite eliciting severe side effects, in particular immunogenicity. We pursue the design of catalytically improved human ASNases and microencapsulation of the enzyme, thus enhancing serum stability and suppressing recognition by the immune system.

5:15 Novel Therapeutic Proteins Derived from Human Protein Synthesis Machinery

Sunghoon Kim, Ph.D., Professor and Director, Medicinal Bioconvergence Research Center, Molecular Medicine and Biopharmaceutical Sciences, Seoul National University
Aminoacyl-tRNA synthetases (ARSs) are essential enzymes for cellular protein synthesis. However, they play diverse physiological roles in extracellular space and their activities show potential for novel therapeutic applications. The extracellular functions of this group of proteins are rapidly being unveiled recently and they are expected to become a resource for novel therapeutic agents. In this context, it is timely and critical to introduce new biology and biopharmaceutical application of these proteins.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:45 Close of Day One

WEDNESDAY, SEPTEMBER 2, 2015

7:45 am Registration and Morning Coffee

ENGINEERING FOR IMPROVED PROPERTIES AND THERAPEUTIC POTENTIAL

8:30 Chairperson's Opening Remarks

William (Jonny) Finlay, Ph.D., Director, Protein Discovery & Optimization, Global Biotherapeutics Technologies, Pfizer Ireland

8:40 Improvement of the Therapeutic Index of Amanitin-Based ADCs



Andreas Pahl, Ph.D., CEO, Heidelberg Pharma

Amanitin-based ADCs represent a new class of ADCs using a novel MOA, inhibition of RNA pol II. The high potency of the toxin leads to highly efficacious ADCs. Here we present the development of technologies and strategies to improve the therapeutic index from the safety point of view. These developments support the clinical development of amanitin-based ADCs by using a toxin with a new MOA and with a favorable therapeutic index.

9:10 Single-Step Ultra-Humanization, Stabilization and Essential Paratope Sampling of Murine, Avian and Leporid IgGs

William (Jonny) Finlay, Ph.D., Director, Protein Discovery & Optimization, Global Biotherapeutics Technologies, Pfizer Ireland

This study presents a technology that generates stable, soluble, ultra-humanized antibodies via single-step CDR redundancy minimization. Lead clones demonstrated high stability, with affinity and specificity equivalent to, or better than, the parental immunoglobulin. This significantly lowered non-human sequence content, minimized

t- and b-cell epitope risk in the final molecules and provided a heat map for the essential non-human CDR residue content of antibodies from disparate sources.

9:40 Engineering Aglycosylated Full-Length IgG Antibodies for Next Generation Immunotherapeutics



Sang Taek Jung, Ph.D., Professor, Department of Bio and Nano Chemistry, Kookmin University

Aglycosylated IgG antibodies shows almost same antigen binding affinity, serum half-life, and biodistribution compared to glycosylated counterpart. However, the removal of N-linked glycan at Asn297 of IgG Fc causes significant change of conformational dynamics and abolishes antibody Fc-mediated effector functions. To restore or enhance therapeutic effector functions, aglycosylated Fc region has been extensively engineered and sets of aglycosylated Fc variants exhibiting novel FcγR binding specificity and unique therapeutic effector functions have been isolated.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 A Single-Chain Fragment against Prostate Specific Membrane Antigen as a Tool to Build Theranostic Reagents for Prostate Cancer

Mariangela Figini, Ph.D., Head, Experimental Oncology and Molecular Medicine, Fondazione IRCCS Istituto Nazionale dei Tumori Milano

In this research we use a single-chain variable fragment (scFv) directed against Prostate Specific Membrane Antigen (PSMA), over expressed in prostate cancer, for therapeutic targeted approaches. A murine anti-PSMA mAbs D2B was converted in a scFv analyzed *in vitro* and *in vivo* for its ability to detect or kill prostate cancer cells. Different approaches for humanization of the scFv have been applied and we propose it as a theranostic reagent.

11:20 Design of Less Immunogenic Drugs Using *in silico* and *in vitro* Tools

Sofie Pattijn, CTO, ImmunXperts

The rapid and exponential growth of therapeutics has also exposed a number of new challenges in drug design and development. One of the major hurdles is the potential of the drug to induce an unwanted immune response. The use of *in silico* algorithms and *in vitro* T cell proliferation assays can guide the design of less immunogenic drugs and support the selection of those candidates with the lowest immunogenicity risk.

11:50 Fast and Flexible Analysis of Fc Receptor Binding Interactions

Craig Tin, Senior Product Manager, Pall ForteBio LLC

Cell mediated effector functions, including the induction of antibody-mediated cell-dependent cytotoxicity (ADCC), by a therapeutic antibody depends on its binding affinity to both the biologic target and to Fc-gamma receptors (FcγRs). Throughout drug development, candidate antibodies are selected, engineered, and characterized by their interactions with FcγRs. A biosensor-based approach to measuring binding affinities allows for quicker results using a high throughput format with the flexibility to be applied from early development to lot release assays.

12:20 pm Networking Luncheon in the Exhibit Hall with Poster Viewing (Sponsorship Opportunity Available)

1:30 End of Protein & Antibody Engineering

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WEDNESDAY, SEPTEMBER 2, 2015

1:00 pm Registration

CANCER IMMUNOTHERAPEUTICS

1:30 Chairperson's Opening Remarks

Ho Cho, Ph.D., Vice President, Biotherapeutics

1:40 New Horizons in Immuno-Oncology: Beyond Check-Point Inhibitors

Ho Cho, Ph.D., Vice President, Biotherapeutics

The recent convergence of enabling technologies with a fundamentally better understanding of the immune system has resulted in new treatment paradigms with unprecedented efficacy for many patients. Building on this success requires an integrated view of the immune system and the tumor microenvironment. This presentation will highlight our recent work on leveraging the innate immune system with an anti-CD47 mAb.

2:10 IL-2 Receptor (IL-2R) Agonist Antibody by Engineering

Cheng-I Wang, Ph.D., Principal Investigator, Therapeutic Antibody Engineering, Singapore Immunology Network

Interleukin 2 (IL-2) is a powerful cytokine that promotes T and NK cells survival and proliferation. While IL-2 is a clinically approved drug to treat certain cancers, its efficacy is limited due to a number of reasons: extremely high toxicity, including fatal pulmonary

edema, preferential activation of regulatory T cells (Treg), and poor PK. In this seminar, an IL-2 receptor agonist antibody engineered in our lab that potentially addresses IL-2's intrinsic problems will be discussed.

2:40 Targeting the Intracellular Proteome with T-Cell Receptor-Like Antibodies

Yoram Reiter, Ph.D., Professor & Head, Laboratory of Molecular Immunology, Technion-Israel Institute of Technology

The ability to generate t-cell receptor-like (TCRL) antibodies which bind HLA-peptide complexes on the surface of cells opens new possibilities for developing new therapeutic modalities. These antibodies can bind specifically to, and kill, the diseased cells, transforming disease-specific targets expressed inside malignant cells into targets that can be recognized on the cell surface by soluble TCRL antibodies. This approach expands the pool of novel therapeutic antibodies beyond the limits of currently available antibodies.

3:10 Sponsored Presentation (Opportunity Available)

3:40 Refreshment Break in Exhibit Hall with Poster Viewing

ANTIBODIES FOR CANCER THERAPY

4:20 Combination of Novel HER2 Targeting Antibody 1A12 with Trastuzumab Shows Synergistic Antitumor Activity in HER2 Positive Gastric Cancer

Kyu-Tae Kim, Ph.D., Director, ADDs, AbClon, Inc.

The synergistic interaction of two antibodies targeting the same protein can be developed as an effective anti-cancer therapy. We describe the development of 1A12, a HER2-targeted monoclonal antibody showing increased efficacy in a highly synergistic manner in combination with trastuzumab. The synergistic antitumor activity of 1A12 in combination with trastuzumab indicates that it could be a novel potent therapeutic antibody for the treatment of HER2-overexpressing gastric and breast cancers.

4:50 Next-Generation Therapeutic Antibody Inhibiting Epithelial Ovarian Cancer Metastasis

Sukmook Lee, Ph.D., Principal Investigator, Research Center, Scripps Korea Antibody Institute

Ovarian cancer metastasis is a complex phenomenon resulting from the coordinated action of many metastatic regulators and must be overcome to improve clinical outcomes for patients with these cancers. Here, we first show the functional relevance between TSPAN8-LEL and ovarian cancer metastasis. By generating a human IgG antibody specific to TSPAN8-LEL, we demonstrate its mode of action, *in vivo* efficacy, and toxicity. Collectively, these data suggest that an antibody to TSPAN8-LEL may have therapeutic potential for the treatment of ovarian cancer metastasis.

5:20 Action Mechanism-Guided Competitiveness Design of GC1118, A Novel Anti-EGFR Antibody

Jonghwa Won, Ph.D., Senior Research Director, Oncology Team, Mogam Biotechnology Institute

EGFR antibodies currently in development are quite different in their forms ranging from antibody mixtures to drug conjugates, action mechanism, and target disease areas. GC1118 has a distinct binding epitope and shows a big difference in the spectrum of EGFR ligands and cancer cell types that are inhibited. Potential hypothesis in working mechanism and clinical implications of GC1118 will be presented.

5:50 End of Day**THURSDAY, SEPTEMBER 3, 2015****8:00 am Morning Coffee****BISPECIFIC ANTIBODIES****8:30 Chairperson's Opening Remarks**

Jin-San Yoo, Ph.D., CEO, President & Founder, PharmAbcine

8:40 Therapeutic Applications of DART® Proteins

Jonathan Li, Ph.D., Scientist II, MacroGenics, Inc.

Bispecific antibodies represent a highly potent class of immunotherapeutic agents that may outperform or complement traditional chemotherapy, naked antibodies and ADCs. MacroGenics' Dual-Affinity Re-Targeting (DART) proteins are among the most stable and potent biologics in this therapeutic class. This talk will highlight several DART proteins currently in clinical studies and those entering clinical studies, as well as new formats and specificities that are under development for future drug candidates.

9:10 Clinical and Preclinical Development on DVD-Ig Dual-Specific Molecules and Next-Generation Multi-Specific Molecules

Tariq Ghayur, Ph.D., Senior Research Fellow & Principal Scientist, Abbvie Bioresearch Center

The DVD-Ig formats enable us to combine the target binding domains of 2 mAbs in a single molecule. Four DVD-Ig molecules are now in clinical development in autoimmune and oncology indications. In this talk I will provide an update on two DVD-Ig molecules in clinical development (RA and OA). In addition, I will discuss recent preclinical developments in extending our multi-specific platforms to address specific unmet clinical needs.

9:40 Clinical Development of Tanibirumab and Next-Generation Bispecific Antibodies

Jin-San Yoo, Ph.D., CEO, President & Founder, PharmAbcine

Tanibirumab, anti-KDR neutralizing fully human IgG1 with unique cross species cross reactivity is in Phase II recurrent GBM trial. I will cover its Phase I data, Phase II protocol for GBM trial and update of Phase II study. PMC-001 (=DIG-KT), next generation of bispecific antibody neutralizing both VEGF-KDR and ANG-TIE2 pathways is in preclinical stage and I will cover the progress report. PMC-008b, anti-EGFRvIII specific human IgG1 for ADC and CAR-T will be introduced.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing**10:40 A Novel Dual Targeting Inhibitor to VEGFR-TIE2**

Ann MacLaren, Ph.D., Vice President, Translational Science, Triphase

Accelerator

Anti-angiogenic agents such as bevacizumab (anti-VEGF) and ramcicirumab (anti-VEGFR2) have proven effective in the treatment of solid tumors. However, tumors can escape the effects of these agents through the TIE-2 axis, activated by angiopoietin. TRPH011 is a dual targeting biologic that blocks both VEGFR2 and TIE2 pathways. The talk will cover *in vitro* and *in vivo* activity of TRPH 011 and our approach to developing dual targeting anti-angiogenic agents.

11:10 A Novel Bispecific Antibody Targeting VEGF and DLL4 Inhibits Tumor Progression

Weon-Kyoo You, Principal Research Scientist, Biologics Unit, Hanwha Chemical

Hanwha has developed a unique novel bispecific antibody targeting VEGF and DLL4. The bispecific antibody has similar activities by various *in vitro* assays compared to VEGF or DLL4-single targeting antibody. In addition, the bispecific antibody more effectively inhibits tumor progression in several xenograft models. These results suggest Hanwha's bispecific antibody could be further developed as a potent anti-cancer therapeutic antibody.

11:40 An Open Cell-Free Protein Synthesis Platform to Discover Novel Antibodies and Bispecifics

Aaron Sato, Ph.D., Vice President, Research, Sutro Biopharma, Inc.

Using our cell free expression platform, Sutro can quickly discover novel antibody fragments (e.g. scFv and Fabs) to any relevant disease target using ribosome display with our bacteria extract system. Finally, we can reformat these antibody leads in a many different bispecific frameworks and test them for binding and functionality. Several case studies will be presented to exemplify the power of this system for antibody and bispecific discovery.

12:10 pm Sponsored Presentation (Opportunity Available)**12:40 Networking Luncheon in the Exhibit Hall with Poster Viewing (Sponsorship Opportunity Available)****ANTIBODY-DRUG CONJUGATES****1:45 Chairperson's Remarks**

Byoung-Chul Lee, Ph.D., Scientist, Protein Chemistry, Genentech, Inc.

1:50 Antibody-Drug Conjugates Targeting Embryonic and Pluripotent Stem Cell Markers as Novel Therapeutics for Metastatic Cancers

Michael Schopperle, Ph.D., CEO, CureMeta

Recent research studies are suggesting metastatic and aggressive cancers are caused by normal cells dedifferentiating or "reprogramming" backwards to an embryonic or pluripotent stem cell state. We have developed several antibodies which are specific for pluripotent stem cells markers and have made several ADCs as novel therapeutics for metastatic cancers. Our studies show that our new ADCs are specific for and highly efficient at killing pluripotent cancer stem cells.

2:20 Imaging Intracellular Activity of Antibody-Drug Conjugates

Byoung-Chul Lee, Ph.D., Scientist, Protein Chemistry, Genentech, Inc.

Despite the recent success of ADCs, their mechanisms of action are not fully understood. In order to gain further understanding of the ADC intracellular uptake and payload release, we developed a novel fluorescence resonance energy transfer (FRET) ADC. This FRET assay will provide a facile and robust assessment of the intracellular processing and have significant implications for the future development and clinical use of ADCs.

2:50 NexMab™, A Site-Specific Antibody-Drug Conjugation Method by Utilizing Ligand-Protected Cysteine-Containing Motifs, and Its Application to Herceptin-Drug Conjugate

Soon Jae Park, Ph.D., CEO, Alteogen, Inc.

We have developed a ligand-protected peptide motifs containing cysteine residues at the C-terminus of antibody heavy chain. This conjugation method, NexMab™, was applied to Trastuzumab (Herceptin®). The resulting drug conjugated mAb (ALT-P7) showed that it did not perturb the stability of the mAb and exhibited a lower aggregation propensity compared with Kadcyla® (ado-trastuzumab emtansine). In mouse Xenograft study with BT-474 breast cancer cell, ALT-P7 displayed higher *in vivo* efficacy compared with Kadcyla®.

3:20 Conjual™ Site-Specific Homogenous ADC Platform with a Novel Linker Chemistry

Jeiwook Chae, Ph.D., Vice President, Biology, Legochem

This presentation illustrates a novel linker chemistry combined with the enzymatic conjugation and shows superb plasma stability. The therapeutic potential of our homogenous ADCs shows improved pharmacokinetics and sustained long-term stability of DAR in rat and monkey as well as high potencies of tumor killing *in vitro* and *in vivo*. This data suggests that Conjual™ ADCs display improved therapeutic indexes and will provide a new clinical opportunity for cancer patients in the future.

3:50 End of Conference

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